INVESTIGATIONS OF THE QUALITY MEDICINES DISTRIBUTED IN MYANMAR AND CAMBODIA, THROUGH DIFFERENT SURVEYS

A DISSERTATION

SUBMITED TO THE DIVITION OF PHARMACEUTICAL SCIENCE

IN PARTIAL FULFILLMENT OF THE REQUIRMENTS FOR THE DEGREE OF DOCTORATE IN PHILOSOPHY

by

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KAKUMA, KANAZAWA, JAPAN
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Dissertation

Investigations of the quality medicines distributed in Myanmar and Cambodia, through different surveys

Graduate School of Medical Science & Technology

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Major Subject: Pharmaceutical Science

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Abstract

Falsified or substandard medicines can present a health hazard to us. We have been attempting to clarify how often we might encounter such medicines and also to identify the specific features of defects to find clues for improvement. Despite of our results, much remains to be studied. Therefore, we reviewed the quality of medicines for lifestyle diseases in Cambodia for three years, and the quality of antimicrobial medicines in Cambodia for four years. In addition, we surveyed counterfeit or substandard medicines in Yangon, Myanmar survey in 2014 for collecting more data.

We conducted a four-year and three-year study to evaluate the quality of selected antimicrobials and lifesaving medicines and to examine the prevalence of falsified or substandard antimicrobial and lifesaving medicines in Cambodia, aiming to promote efforts to improve the quality of medicines. We collected samples of clarithromycin, sulfamethoxazole/trimethoprim, ceftriaxone, cefuroxime, levofloxacin, gentamicin, ciprofloxacin, fluconazole, nalidixic acid, ofloxacin, phenoxymethyl penicillin and roxithromycin medicines as well as cimetidine, amlodipine, esomeprazole, rabeprazole, glibenclamide and metformin from pharmacies, Depot-A, Depot-B, wholesalers and non-licenced drug outlets in five provinces (rural areas) and Phnom Penh (an urban area), during 2011 to 2014 (antimicrobial) and 2011 to 2013 (lifesaving). The authenticity of the collected medicines was investigated, and the medicines were

analyzed to determine whether they met the appropriate pharmacopoeial standards. We collected 647 samples, produced by 179 manufacturers, from 353 outlets. Only 51 (15%) of the outlets were air-conditioned. We found different-coloured packaging of the same brand (different lots) of products from some manufacturers. The insert information of one sample was different from the package information. Twelve (1.9%) samples were not officially registered with DDF. In authenticity investigation, 43 of 179 manufacturers replied and confirmed the authenticity of 154 samples (out of 647); also, 18 out of 54 MRAs replied to enquiries about whether products were licensed or not (one was not). Among the samples, 84 (16.5%), 58 (12.5%) and 47 (8.1%) failed in dissolution, content uniformity and quality tests, respectively. Samples of cefuroxime and roxithromycin that failed were significantly cheaper than those that passed. Poor-quality antimicrobial medicines were found in Cambodian markets, though no falsified medicines were detected. Manufacturers should be encouraged to improve GMP implementation. Storage conditions in the distribution chain may also need to be improved. Continuous efforts by MRAs are needed to ensure that medicines are properly licensed.

In the case of three-year survey, we found 342 samples (223 from Phnom Penh) were collected from 263 outlets; among them, 32 (9.4%) had no inserts, and 14 (4.1%) were not registered with DDF. 38 (11.1%) were domestically produced. The containers

of one amlodipine and three cimetidine samples were different from those of authentic samples. Nonstandard inserts were found in two samples (amlodipine and metformin). Only 21/81 manufacturers and 16/35 MRAs replied during authenticity investigation. In quality evaluation, 38 (11.1%), 52 (15.2%) and 48 (14%) samples failed dissolution, content uniformity and quantity tests, respectively. The failure rate in quality tests was significantly associated with the results of visual analysis of samples. Poor-quality medicines were prevalent in Cambodia in 2011-2013. Further surveys should be conducted to monitor the situation. Measures are desirable to improve the quality of domestically manufactured products.

We also investigate the current situation of substandard or counterfeit medicines in Myanmar. Samples of oral medicines, cefuroxime axetil (CXM), donepezil hydrochloride (DN) and omeprazole (OM), and injections, ceftriaxone sodium (CTRX) and gentamicin sulfate (GM), were collected from pharmacies, hospitals and wholesalers in Yangon, Myanmar in 2014. Authenticity and registration were verified. Quality tests of samples were performed according to the pharmacopeia indicated on the label. There were 221 (94%) foreign medicines among 235 samples collected from 75 locations. Five samples of GM and 1DN sample were not registered with Myanmar Food and Drug Administration (MFDA). In quality analysis, 36 samples out of 177 (20.3%) did not pass quantity tests, 27 samples out of 176 (15.3%) did not pass content

uniformity tests, and 23 out of 128 samples (18.0%) did not pass dissolution tests. Three of the unregistered GM samples failed in both identification and microbial assay tests. Counterfeit GM is being sold in Yangon. Also, the quality of OM is a matter of concern, and requires follow-up. Poor-quality medicines were frequently found among the products of a few manufacturers. Regular surveys to monitor counterfeit and substandard medicines in Myanmar are recommended.

We found that poor-quality medicines are the urgent problems in Cambodia and Myanmar, even though the medicines were not counterfeit. Serious dissolution failure is the dominant problem in these countries. It is necessary to collect more information of such medicines, and to analyze the characteristics of the data for preventing health hazards caused by falsified or substandard medicines.

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In fine, all praises go to Almighty Allah, the omniscient and the most merciful.

The Author

Dedicated to

the memories of

2011 Tōhoku earthquake and tsunami victims

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General Introduction:

Medicine is one of the most essential elements especially for human being to survive in the in the world. People used different types of plants for their treatments before 5000 years [1] however, now in modern world patients are using biotech medicines like as insulin, interferon, interleukin and so on [2]. Sir Alexander Fleming discovered the benzylpenicillin (Penicillin G) from the mould *Penicillium_notatum* in 1928 [3], since then patients in the world wants to use particular elements (active ingredient) for their treatments. From the historical reason and requirement in the world manufacturers are producing lot of medicines and supplying to the markets. Some manufacturers are taking a chance and preparing counterfeit or falsified or poor quality medicines and supply to the markets. These types of medicines are accessed in both developed and developing countries [4-6]. One investigation was occurred and found around 1% and 10% in developed and developing countries, respectively [7]. People are suffering and even died due to effect of counterfeit / falsified / substandard / poor quality medicines which evidences were already established in the world [8-10]. Perception from the above of story the governments of Myanmar and Cambodian were started more than one collaborative projects with Kanazawa University investigated to observe their own situations and evaluate the quality of selected medicines through different surveys.

Chapter One:

An investigation into the quality of medicines in Yangon, Myanmar survey in 2014

1.1 Introduction

Medicines are the most essential elements especially for human beings for surviving their lives in this world. It is almost impossible to imagine the remedy of human body from various diseases without taking good quality of medicines. Deliberately, many pharmaceuticals have been producing counterfeit medicines and supply to the patients as well as they are taking a chance to earn more money by producing such detrimental counterfeit medicines and even extending their imposture day by day. This is also happening in both developed and developing countries [4-6]. In this vast sector it is very difficult to optimize the counterfeit medicines. Depending on geographic region the range of counterfeit drugs supply to the developed countries as well as the rising countries are about 1% and 10%, respectively [7]. Another investigation from the World Health Organization (WHO) about 20%-90% falsified medicines were found in several Africa countries [11, 12]. The incidence due to counterfeit medicines were estimated in Cambodia with the range of 4%- 90% from 2001 to 2010 [13-16]. Furthermore, owing to fake medicines around 200 children were died in Bangladesh in 1990–1993 ingesting counterfeit paracetamol that contained diethylene glycol [17].

In Myanmar, a massive investigation occurred by World Health Organization (WHO) in 1999 and caught counterfeit medicines [18]. It is very difficult to identify such

counterfeit medicines however it is also possible to buy good quality medicines. The problem is that the sellers demand extra money for good quality medicines which is illegal and unethical. For this reason, an emergency cases, people suffer or may die for the prevalence of counterfeit drugs [17, 19]. In most cases the patients from developing counties do not want or cannot fulfill antibiotic courses due to their economic crisis. Thus the misuses or inadequate doses of antibiotics may guide them to the advance of resistance [20] while support the extra food demands of the rising population of the world antibiotics are using in husbandry sectors specially in poultry industry as a growth promoter and transmitted to the human that is occurred resistance by several types of microorganisms particularly in bacteria [21, 22].

Counterfeiting or poor quality antibiotic is Worldwide spreading that is one of the biggest and vital factors and is making sub-inhibitory concentrations naturally and enhance the selection of resistant strains from various types of microorganisms [23, 24].

1.2 Aim of This Work

People in low income countries are suffering in counterfeit or poor quality medicines in their daily life. People in this type of country are almost depending on foreign country medicines. In 1999, a massive investigation occurred by WHO to evaluate the quality of medicines and found counterfeit medicines in Myanmar. Since then there

were no systematic survey conducted on medicines in Myanmar. We want to investigate the quality of medicines which associate outlet condition, outlet types, price of medicine, type of medicines (domestically produced or not) and medicines entered in to Myanmar that is needed to fulfil Myanmar government policies. Finally, we suggested to the government of Myanmar how to remove counterfeit or poor quality medicines from Myanmar markets.

1.3 Sample Collection

From the suggestions of Myanmar FDA (MFDA), we selected a populated region as well as from the MFDA essential drugs list, we selected five types of medicines. Samples of oral medicines, cefuroxime axetil (CXM) [25], donepezil hydrochloride (DN) and omeprazole (OM) [26] and injections, ceftriaxone sodium (CTRX) and gentamicin sulfate (GM) [27] were purchased during 27 September- 4 October 2014 by two teams from Yangon, Myanmar (Annex 1.1). Each team consisted of one supervisor from MFDA, one local assistant and one or two Japanese researcher (s). All team members received training before starting the sampling work. During the sampling period, we maintain a sampling form for each number of samples (Annex 1.2). We collected samples from the governmental hospital and private hospital as well as community pharmacies, clinical

pharmacies and wholesalers. Obtained samples were stored at 20-25ºC before analyzed in Kanazawa University, Japan.

1.3.1 Observation Analysis

During the sampling we observed room conditions like as temperature, humidity and also observed in both internal and external environmental conditions around the surrounding of the retail shops. After sampling, the obtained samples were checked physical shape, size of sample volume or shape, uniform colour, insert, spelling, registration number from MFDA, manufacturing date, expire date, lot no., name of active ingredient, doses form etc. that were utilized in the form of the "Tool for Visual Inspection of Medicines" (Annex 1.3) [28]. For establishing the evidences, photographs were taken for each samples with scanned insert and the sample box.

1.3.2 Sample Authenticity Investigation

The authenticity investigation and registration verification was performed according to the modification method of World Health Organization (WHO) [16]. We asked some questions to the responsible manufacturers by using a form (annex 1.4) with sent scan copy of the samples box, samples photographs and insert of the sample by E-mail (annex 1.5). At the same time, we asked to the Medicine Regulatory Authority

(MRA) of each country regarding the medicines were registered or not (annex 1.6). While, we asked to the MFDA about obtaining medicines were registered or not.

1.3.3 Samples for Chemical Analysis

Samples were evaluated according to the pharmacopeia that mentioned on the package of the samples. In the following method we used and evaluated our collected samples. Our collected cefuroxime samples 250 mg tablets were performed dissolution, content uniformity and quantity test. To determine the amount of cefuroxime ($C_{16}H_{16}N_4O_8S$) dissolved by employing UV absorption at the wavelength of maximum absorbance at 278 nm on filtered portions of the solution under test, suitably diluted with dissolution medium 0.07N Hydrochloric Acid; 900 ml, if necessary, in comparison with a standard solution having a known concentration of UPS cefuroxime axetil RS, equivalent to about 0.01 to 0.02 mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per ml, in the same medium. 55 rpm (for test 1) and 100 rpm (for test 2) were used during the dissolution test, while samples considered at 15 and 45 minutes not less than 60%, 75% for 1^{st} stage and 50% ,70% for 2^{nd} stage gradually. 0.2 M monobasic ammonium phosphate (purchased from Nakalai Tesque Kyoto, Japan) dissolve 23.0 gm of monobasic ammonium phosphate in water to preparer 1000 ml of solution. 620 ml solution were taken from 1000 ml and added 380 ml methanol (Wako, Japan) to make 1000 ml mobile phase. 5.4 mg

acetanilide dissolved in per ml methanol to preparer internal standard solution. For Resolution Solution, mix 10.0 ml of a solution of USP cefuroxime axetil RS in methanol containing 1.2 mg per ml then transfer in a 50 ml volumetric flask and including of 5.0 ml of internal standard solution with 3.8 ml of a solution of cefuroxime axetil Delta-3 Isomers RS in a methanol containing 0.16 mg per ml. Finally, to fill with dilute with 0.2M monobasic ammonium phosphate to make the target the volume, and well mix. For standard preparation, transfer 30 mg of USP cefuroxime axetil RS to a 25 ml volumetric flask dissolve dilute to make the volume. Promptly transferred 10.0 ml of this solution to another 50 ml volumetric flask then added 5.0 ml of internal standard solution and 3.8 ml of methanol, finally added dilute to make the volume. In assay preparation, fine powder not fewer than 10 tablets were accurately counted. Transfer the powder, with the aid of methanol, to a volumetric flask of such capacity that when filled to volume, the solution will contain the equivalent of about 2 mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per ml. Added methanol to fill the volumetric flask to about half of its capacity, and shake by mechanical means for about 10 min. Dilute with methanol to volume, and mix. Filter a portion of this stock mixture, and transfer 5.0 ml of the filtrate to a 50 ml volumetric flask. Add 5.0 ml of internal standard solution and 8.8 ml of methanol dilute with 0.2 M monobasic ammonium phosphate to the volume, and mix. The HPLC system from JASCO (Tokyo,

Japan) were maintained 278 nm UV detector, 4.6 mm x 25 cm; 5µm packing L13 column, 40^0 C column oven temperature, flow rate 1.2 ml/min and injection volume 10 µl. In quantity analysis 90.0≦mean≦110.0 and content uniformity AV≦15.0 were followed [29], cefuroxime peak observed (Figure 1.1). The linearity of the standard cefuroxime/diluent solution was maintained and analyzed between 0.025 and 0.5 mg/ml and the 0.6 to 0.5 (Figure 1.2).

Figure 1.1 Chromatogram of cefuroxime (standard)

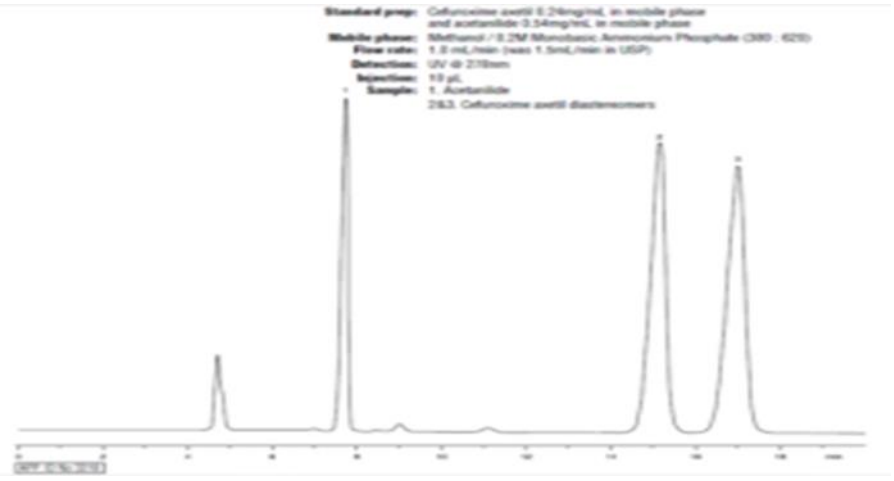
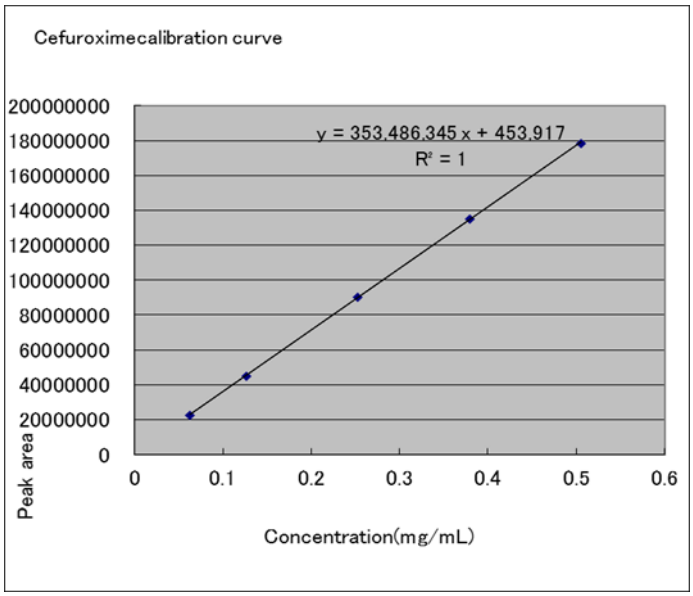


Figure 1.2 Linearity of cefuroxime solution, using acetanilide as an internal standard.



For content uniformity test of ceftriaxone for injection (1 gm vial) at first we prepared P^H 7.0 buffer, dissolve 17.415gm of dibasic potassium phosphate in 500 ml of water and dissolve 13.605 gm of monobasic potassium phosphate in 1000 ml of water. Control the p^H of dibasic potassium phosphate solution to p^H 7.0 by using monobasic potassium phosphate solution. p^H 5.0 buffer, dissolved 12.9 gm of sodium citrate in 250 ml of water and dissolved 9.6 gm of citric acid in 500 ml of water. Control the p^H of sodium citrate solution to p^H 5.0 by using citric acid solution. Dissolved 3.2 gm of tetraheptyl ammonium bromide were taken in 400 ml of acetonitrile, added 44 ml of p^H 7.0 buffer and 4 ml of p^H 5.0 buffer, and added water to make 1000 ml to make the mobile phase. 0.5 µm membrane filter was used then allow to degas. 450 ml Acetonitrile were taken into the 1000 ml volumetric flask then added water up to the volume for diluents as

well as IS preparation 5 mg of diethyl terephthalate were taken to dissolve in diluents and make up to the volume 50 ml. Regarding the standard solution preparation, 5 mg of ceftriaxone sodium RS were transferred to 50 ml volumetric flask, and dilute with diluents to the volume (0.1 mg/ml) then 2 ml of these solutions were transferred into 10 ml volumetric flask (20µg/ml) to make 200%. Mixed 3 ml of 20µg/ml solution and 1ml of diluents (15 µg/ml) to make150%. Mixed 2 ml of 20µg/ml solution with solution 2 ml diluents (10 µg/ml) for 100%. Again mixed 2 ml of 10 µg/ml solution with 2 ml of diluents (5 µg/ml) to make 50% of the solution. While, mixed 2 ml of 5 µg/ml solution and 2 ml of diluents then prepared (2.5 µg/ml) 25% of the samples. Mixed 1 ml of each (200%, 150%, 100%, 50% & 25%) of this solution with 1 ml of IS solution for linier carve. During the assay preparation, 1 gm ceftriaxone sodium were transferred to a 100 ml volumetric flask then added diluents to the volume. Transferred 1 ml of this solution to 50 ml volumetric flask and added with diluents to the volume. Mix 0.5 ml of this solution and 2.5 ml of diluents. Mix 1 ml of this solution and 1 ml of IS solution. In chromatographic system 270 nm detector, 4.0 x 10 cm column, 2.0 ml/min flow rate, injection volume and 40^0C oven temperature were maintained. In quantity analysis 90.0≦mean≦115.0 and content uniformity AV≦15.0 were followed [30].

Donepezil samples were investigated according to the Japanese Pharmacopoeia 16th edition (JP 16). 2.5 gm of sodium-1 decane sulfonate were dissolved in 650 ml of water, and added 350 ml of acetonitrile, 1 ml of per chloric acid to make mobile phase, then to prepare standard solution and weighed accurately about 50 mg of JP donepezil hydrochloride RS, and dissolved in diluent-1 (Methanol and 0.1 mol/L hydrochloride 3:1) to make exactly 25 ml. Transfer 5 ml of this solution to a suitable test tube, added diluent-1 to make exactly 50 ml. For assay preparation, one tablet of donepezil hydrochloride with added diluent-1 so that it contained the concentration about 0.2 mg per ml then sonicate and properly mix until a tablet is disintegrated for 10 min. After sonicate then centrifuge for 4000 rpm for 15 min with continued 25℃ and supernatant solution were taken. For dissolution test was performed at 50 revolutions per minute according to the puddling method as directed under the dissolution test in JP16, using 900 ml of the dissolution medium. After the dissolution, performed the test with 50 µl each of the sample solution and standard solution as directed under Liquid Chromatography in JP16 followed and calculate the ratios of AT and AS, of the peak area of donepezil hydrochloride. 3.4 gm Potassium dihydrogen phosphate and 3.55 gm of sodium dihydrogen phosphate were taken in 1000 ml water to make the phosphate buffer. Phosphate buffer (pH 6.8) and water (1:1) were used as a dissolution medium. Mightysil

RP 18GP 150×4.6 mm (5 µm) column, wavelength 271 nm, 35℃ in column temperature, 1.0 ml/min flow rate, 50 µl injection volume, mobile phase: water, acetonitrile and per chloric acid (650:350:1) were used in this test. To make the standard solution we weighed accurately about 20 mg of JP donepezil hydrochloride RS with dissolve in diluent-1 to make exactly 20 ml. 1 ml of this solution were transferred to a suitable test tube then added with the dissolution medium to make exactly 100 ml. In addition, transferred 5 ml of this solution to a suitable test tube and added the dissolution medium to make exactly 10 ml solution. The sample solution was withdrawal not less than 20 ml of the medium at 15 min, after starting the test and filtered with a membrane filter which contained the pore size of 0.45 µm. Discard the first 10 ml filtrate of the sample then transfer the subsequent filtrate to a suitable test tube. Not less than 80 % of the labeled amount of donepezil hydrochloride ($C_{24}H_{29}NO_3 \cdot HCl$) is dissolved in 15 min were considered [31].

Identification was performed on the gentamicin samples. 1gm of o-phthalaldehyde in 5 ml of methanol and added 95ml of 0.4 M boric acid that previously adjusted with 8 N potassium hydroxide to a p^H of 10.4 and 2 ml of thioglycolic acid. Adjust, obtained of the solution with 8 N potassium hydroxide to a pH of 10.4. To prepare the mobile phase and maintained the ratio of methanol, water and glacial acetic acid

(68:27:5) as well as 5gm of sodium 1-heptanesulfonate were added per liter to this solution. Then standard solution was prepared to use of USP gentamicin sulfate RS in water to make the concentration of 0.65mg per ml. 10 ml of this solution were transferred to a suitable test tube and added of 5ml of isopropyl alcohol with 4 ml of o-phthalaldehyde solution then properly mix and finally isopropyl alcohol were added to obtain 25 ml of solution. At 60°C tempereture were maintained in a water bath for 15 minutes then cool. In the case of sample solution preparation, 1ml of the sample were taken and mix with 60.5 ml of water. Taken 10 ml from the mixture transfer to a suitable test tube with added 5ml of isopropyl alcohol as well as 4 ml of o-phthalaldehyde solution then properly mix and finally added isopropyl alcohol to obtain 25 ml of solution. At 60°C tempereture were maintained in a water bath for 15 minutes then cool. Phenomenex Luna C18 L1 150×4.6 (mm) column, 1.0 ml/min flow rate, 330 nm UV detector and 20 µl injection volume were used in the chromatographic system. In analysis part, we compared the peak of the sample with that of the RS to quantitate GM, and determine whether any impurity peaks appear in the chromatogram [32].

Content uniformity test in omeprazole at first to make for the solution A (1L) 10.454 gm tri-sodium phosphate 12-water and 15.616 gm disodium hydrogen phosphate were taken in a 1000 ml volumetric flask. Suitable amount of distill water were added

and sonicate to dissolve it. Adjust the volume with distill water then adjust the p^H to 11.0 ± 0.05 with 10 M sodium hydroxide or orthophosphoric acid were used. For solution B (500 ml) 5 ml of 10 M NaOH were taken in 500 ml volumetric flask. To make the volume of 500 ml with 0.05 M phosphate buffer solution p^H 4.5 and well mix. In 1 L phosphate 6.8 gm potassium dihydrogen were taken in a 1000 ml volumetric flask and added suitable amount of distill water to dissolve and used a sonicate, adjust the volume and then filter by a vacuum filter and degas it. 210 ml of 0.05 M phosphate buffer solution (p^H 4.5) with 60 ml of solution B were mixed, from it 200 ml solution were taken in a 1000 ml volumetric flask and make volume with solution A. Finally, this solution used for diluent. Regarding the mobile phase, 1.17 gm of sodium dihydrogen phosphate dihydrate ($NaH_2PO_4.2H_2O$) were taken in a 500 ml volumetric flask, allow to the sonicator for dissolved and added with dilute to the volume. In another 500 ml volumetric flask was taken and transferred 1.06 gm of disodium hydrogen phosphate (Na_2HPO_4) dissolve in diluent and make sure the volume. Transferred the $NaH_2PO_4.2H_2O$ solution to a 1000 ml beaker and adjust the p^H to 7.6 ± 0.05 with Na_2HPO_4 solution in a p^H meter. For 1 Liter of mobile phase 600 ml of this solution were taken in a 1000 ml volumetric flask and added 400 ml of acetonitrile (60:40 ratio). Filtered the solution in a suction filter and then degas the mixture in a sonicator for 30 minute. For standard solution preparation 10 mg

of omeprazole RS were weighted and dissolve to a 50 ml volumetric flask with medium in a sonicator than sure to make the final volume and properly mix which was 200% (solution concentration 0.2mg / ml). From this concentration of the solution with medium to make 150%, 100%, 50% and 25% of solution. while weighted accurately about 10 mg of lansoprazole were dissolved to a 100 ml volumetric flask with medium in a sonicator, make final volume and mix for IS preparation (0.1 mg/ml). Transferred 1 ml of 200% ~ 25% to each test tube with 1 ml IS added to each mix then allow to filter and put it in 1 ml vial. For assay preparation in content uniformity, 10 capsules granules were transferred in 50 ml volumetric flask. Dissolved the capsules with diluent in a sonicator and continue sonication until it dissolves. Transferred 1 ml from each to 10 test tube and added 3 ml of diluent and mix then filtered of the sample by 0.45 μm filter paper, 1 ml of this solution was taken and added 1 ml of IS solution with well mix and transferred to 1 ml vial. 4.6 mm × 150 mm column (C18) column, 302 nm wavelength, 30^0 C column oven temperature, 0.5 ml/min flow rate and 10 μl injection volume were maintained in chromatographic system. In quantity analysis 95.0≦mean≦105.0 for BP as well as 90.0≦mean≦110.0 for USP and content uniformity were followed in AV≦15.0 [33-35]. In dissolution test for omeprazole samples were performed according to BP and USP that were mentioned on the package label. Regarding the dissolution test in BP, solution A

and solution B were used as well as to prepare solution C with 1.170 gm Sodium dihydrogen phosphate dihydrate and 1.061 gm disodium hydrogen phosphate were taken in a separate 500 ml volumetric flask. Suitable amount of distil water were used then allow for sonicate to dissolve and then adjust volume. Added 400 ml of disodium hydrogen phosphate to 500 ml of sodium dihydrogen phosphate dihydrate and adjust p^H to 7.6±0.05. We prepared the mobile phase and 400 ml acetonitrile with 600 ml of solution C were properly mixed (p^H 7.6±0.05) then filter it in a vacuum filter and degas it for 30 minute in a sonicator. At that time, we prepared this solvent, 13.6 gm potassium dihydrogen phosphate were taken in a 2000 ml volumetric flask with added distil water to dissolve in a sonicator (about 10 min), adjust the volume and allow for filter by a vacuum filter then degas it. For the first stage, 0.05 M phosphate buffer solution p^H 4.5 and solution A (1:4, v/v) as well as in the final stage, 0.05 M phosphate buffer solution p^H 7.6 and solution A (1:4, v/v) were mixed to make the diluent. In the dissolution tester water were transferred before test, to keep warmed to 37 ± 0.5 °C. Measure the degassed solvent 700 ml in a graduated cylinder and put it in the vessel. Filled all the six vessels following the first one. Mount the paddle up, then lower it to the original position when temperature reaches to the desired level, set rotational speed to 100 rpm. Put the weighed samples, in each vessel in 1 min interval. In acid stage (p^H 4.5), after 45-minute elution,

5ml medium were withdrawal and filter the aliquot of dilute to 25 ml with solution A in a 25 ml volumetric flask then transferred 1 ml of this test solution to a test tube with added 1 ml IS solution to it and properly mixed. Proceed immediately to the final stage. Preparation of standard we used, 1) 40 ml of 0.05 M phosphate buffer solution (p^H 4.5) were taken in a 200 ml volumetric flask and fill it up to the mark with solution A (Solution D). 2) Accurately weigh 5 mg of lansoprazole IS were put in 50 ml a volumetric flask, added a suitable amount of Solution D, sonicate for 10 minutes to dissolve and then make it up to 50 ml with solution D (0.1mg/ml). Taken 1 ml of this solution to place it in a volumetric flask of 10 ml and filled up with Solution D (IS solution with 10 µg / ml). 3) Accurately weigh 5 mg of Omeprazole RS and put in a volumetric flask of 50ml, add an appropriate amount of Solution D, sonicate for 10 minutes to dissolve, and make volume (0.1mg/ml). 2 ml of this solution were transferred to 10 ml volumetric flask and dilute it up to the mark with solution D 200% solution (concentration of 20 µg/ml). From this concentration of this solution with diluent to make 150%, 100%, 50% and 25% of the solution. Transferred 1 ml from solution 200% ~ 25% to each test tube and added 1 mL IS to each with mix then filter and put it in 1ml vial. For the buffer stage (pH 6.8), within 5 minutes of the 200 ml of solution B at 37±0.5^0 C were added to each vessel. The rotation speed at 100 revolutions per minute was controlled and continue to operate the apparatus

for 45 minutes as well as again 5 ml of the dissolution medium were withdrawn 45 minutes, after starting the test and transferred to a 25 ml volumetric flask, make sure to the volume with dilute then 1 ml of above test solution were transferred to a test tube and added 1 ml of IS solution with well mix. Regarding the buffer stage again we prepared for standard, 1) 21 ml of 0.05M phosphate buffer solution (p^H 4.5) were mixed with 6 ml of Solution B, from this solution 20 ml were transferred in a 100 ml volumetric flask and make volume with solution A (Solution E). 2) 5 mg Lansoprazole were transferred in a 50 ml volumetric flask with added the suitable amount of solution E and sonicate for 10 minutes to dissolve then actual make the volume (0.1mg/ml). Taken 1 ml from it to a 10 ml volumetric flask then make volume with solution E that was IS solution. 3) 5 mg omeprazole RS were put in a 50 ml volumetric flask, added a suitable amount of solution E and sonicate for 10 minutes to dissolve then make volume (0.1mg/ml). From this volume 2 ml were placed in a 10 ml volumetric flask and filled it up with Solution E (20µg / ml) and obtained 200% solution. From 200% solution with diluent used to make 150%, 100%, 50% and 25% of the solution. Transferred 1 ml from solution 200% ~ 25% to each test tube and added 1 ml of IS to each with mix then allow to filter and put it in 1ml vial. In chromatographic system 302 nm detector, Gemini-NX column, 0.5 ml/min flow rate, 30℃ temperature and 10µl injection were used. In acid stage, no individual

unit exceeds 10% dissolved and buffer stage no unit is less than Q+5% (Q= 65%) were considered. According to the USP dissolution method, for the mobile phase we used 340 ml of Acetonitrile to a 1000 ml volumetric flask, dilute with p^H 7.6 phosphate buffer to the volume then allow for filtration through membrane filter then degas for 30 minutes. 1) For Acid Resistance Stage, 40 ml of 5N HCl were measured exactly and placed it in a 2000 ml volumetric flask dilute were used to make the volume (0.1NHCl). 2) pH 10.4, 0.235M disodium hydrogen phosphate (For 1L) 2.4 L for Buffer Stage 33.36 g of disodium hydrogen phosphate were dissolved in 1000 ml of water and adjust with 2N sodium hydroxide for p^H of 10.4 ± 0.1. 3) pH 6.8 phosphate buffer (900mL), 500 ml of 0.1N hydrochloric acid were added with 400 ml of disodium hydrogen phosphate p^H 10.4. 0.235 M dibasic sodium phosphate ($Na_2HPO_4.7H_2O$) were used to adjust with 2N hydrochloric acid or 2N sodium hydroxide, if necessary to the contain of p^H of 6.8 ± 0.05. 4) p^H 7.6 phosphate buffer (1L) for the mobile phase, 0.178 gm sodium dihydrogen phosphate and 1.12 gm disodium hydrogen phosphate were transferred in a 250 ml volumetric flask and dissolve it with distilled water. If necessary, adjust to p^H 7.6 ± 0.1 with utilized 2N sodium hydroxide or 2N hydrochloric acid. Total solution was transferred to 1000 ml volumetric flask and make the volume with dilute. 5) For 0.01M sodium borate solution (1L), 3.8137 gm of Sodium tetra-borate decahydrate (Borax) were

taken in a 1000 ml volumetric flask and make the volume with distilled water. Regarding the dissolution of the Sample, water was pre-fill to the dissolution tester and to keep warm to 37.0 ± 0.5 ℃. 500 ml of media (0.1 N HCl) were placed in each of the six dissolution vessels. The apparatus was assembled and warm the media to 37^{o} ± 0.5^{o}C. Weigh and place pellets equivalent to 20 mg omeprazole were maintaining one-minute interval in each vessel and immerse paddle in media to a distance of 2.5 ± 0.2 cm between the paddle and bottom of the vessel. Analyze the sample by the following HPLC method. For the acid resistance stage in standard solution, 40 ml methanol were transferred in 200 ml volumetric flask than added with 160 ml of 0.01 M sodium borate solution for diluent preparation. To prepare the IS solution, 5 mg Lansoprazole RS were used and put it in a 50 ml volumetric flask as well as added a suitable amount of diluent allow to sonicate for 10 minutes for dissolving and then make it up to 50 ml with diluent (0.1mg/ml). From this solution 1 ml were taken and placed in a10 ml volumetric flask with filled up with solution D. To make the WS solution, put 5 mg of accurately weighed omeprazole RS into 50 ml volumetric flask with added an appropriate amount of diluent to allow sonicate for 10 minutes then filled the volume with diluent. 4 ml solution were put in a10 ml volumetric flask of and make up to volume with diluent for 200%) Solution. From 200% solution with diluent to make 150%, 100%, 50% and 25% of the solution. Transferred 1

ml from solution 200% ~ 25% to each test tube and added 1 ml IS to each as well as mix to allow filter and put it in 1ml vial. In the case of test solution, after 2 hours filtered the dissolution medium which were containing the pellets through a sieve with an aperture not more than 0.2 mm. Collected the pellets on the sieve and rinse them with water and were using approximately 60 ml of 0.01M sodium borate solutions with carefully transfer the pellets quantitatively to a 100 ml volumetric flask then sonicate for about 20 minute until the pellets are broken up. Added 20 ml of methanol to the flask with dilute of 0.01M sodium borate solution to volume and properly mix. Dilute an appropriate amount of this solution with 0.01M sodium borate solutions were obtained a solution which having a concentration of about 0.02 mg per ml. Filter the solution through Whatman No. 42 or equivalent omeprazole filter paper were used. Then filter the filtrate again done through syringe filter of 0.20 micron. During the buffer stage, proceed as directed for Acid resistance stage with accurately weighed fresh pellets from the same batch. After 2 hours 400 ml of 0.235M dibasic sodium phosphate were added to the 500 ml of 0.1N hydrochloric acid medium in the vessel as well as of adjust, if necessary, with 2N hydrochloric acid or 2N sodium hydroxide to a p^H of 6.8 ± 0.05 were used. At the end of 30 minutes, determine the amount of omeprazole dissolved in p^H 6.8-phosphate buffer. Regarding the test solution (for 20 mg display of capsule), after dissolution for 30

minutes, immediately transferred 5 ml of the solution under test to a test tube which containing 1 ml of 0.25 M sodium hydroxide, well mix well and filter the solution through Whatman No. 42 or equivalent filter paper. Then filter the filtrate again through syringe filter of 0.20 micron. To prepare the standard solution, 200 ml p^H 6.8 phosphate buffer with 40 ml 0.25 M sodium hydroxide were used for diluent as well as in the IS solution, accurately 5 mg Lansoprazole RS were weighed and put it in a volumetric flask of 50 ml with added a suitable amount of the diluent then sonicate for 10 minutes to dissolve with the making for 50 ml which containing of the diluent, from this solution taken for 1 ml and placed it in a volumetric flask of 10 ml fill up with solution D. Then we were making the WS solution and put 5 mg of accurately weighed omeprazole RS into 50 mL volumetric flask with added an appropriate amount of diluent then allow for sonicate for 10 minutes finally to prepare the volume with diluent. Transferred 4 ml solution in a volumetric flask of 10ml and filled the volume with diluent which was 200% solution. From this solution (200%) with diluent to make 150%, 100%, 50% and 25% of the solution. Transferred 1 ml from the solution of 200%~ 25% to each test tube and were added 1 ml of the IS solution to each and well mix allow to filter and put it in 1ml vial. In chromatographic system 280 nm detector, 4.0 mm×12.5 cm including packing L7 of 5µm of column, 1.0 ml/min flow rate and 10 µl injection volume were used. In acid

resistance stage tolerance, level L1 individual data will not exceed 15% of the omeprazole dissolved, for the level L2 of 12 average units within 20% dissolved omeprazole in individual data will not exceed 35% omeprazole dissolved. Regarding the level L3of 24 within 20% of the average dissolution omeprazole units, greater than 35% of the maximum in also dissolved within 2 units is omeprazole, individual units is not greater than 45% of omeprazole dissolved. While in the case of buffer stage, level B1 Each unit is not less than Q+5% (Q=75%) and the level B2 average of 12 units was equal to or greater than Q and no individual unit were less than Q-15%, finally the level B3 average of 24 units is equal to or greater than Q and not more than 2 units were less than Q-15% and no unit was then Q-25%.

In our investigation, we caught counterfeit gentamicin samples. For this reason, we further investigation in this way to use fluorescence spectrophotometer and observed and compare in pass and counterfeit samples. In fluorescence spectrometry both an excitation spectrum (the light that is absorbed by the sample) and/or an emission spectrum (the light emitted by the sample) can be measured. The concentration of the analyte is directly proportional with the intensity of the emission with excitation of wavelength.

1.3.4 Samples for Biological Analysis

Our collected gentamicin samples (injection) which were performed in microbial assay according to the analysis of USP. Regarding this test, Staphylococcus epidermidis ATCC 12228 strain were performed during this test. We used Base layer media which consists of peptone, pancreatic digest of casein, yeast extract, beef extract, dextrose, agar and water (12:8:6:3:2:32:2000) and controlled the p^H 6.6±0.1. culture organisms were transferred in this media. 16.73 gm/l of diabasic potassium phosphate and 0.523g/L of monobasic potassium phosphate were mixed to make 0.1 M buffer with adjust the pH to 8.0±0.1 with 18 N phosphoric acid or 10 N potassium hydroxide. Microorganisms were suspend in 10 ml saline and adjust the solution to give a transmittance of around 1.0% at 580 nm as a solution. For the standard solution, we weighted 10 mg of gentamicin RS and dissolve in 10 ml of the buffer solution. From the serial dilution we prepared the standard solution 5 (4.0 gm/ml), solution 4 (3.0 gm/ml), solution 3 (2.286 gm/ml), solution 2 (1.0 gm/ml) and solution 1 (0.5 gm/ml). Also, prepared a control solution which were containing 2.0 gm/ml (＝590 ug/mg as potency) of gentamicin RS. To make the sample solution,1ml of the solution from the ampoule (sample) were taken and added to a flask with adjust to 17576 fold dilution of buffer (= 2.2758 gm/ml) then transferred the

solution to a clean bench, allow for filter and place it a 2 ml tube. In this method we maintain the following procedure, at first we injected 100 ml of microrganism solution on the base layer, and spread with a turn table and spreader. At least five test plates are needed to make the standard curve. Second, place four cylinder-cups on each plate. Third, injected 250 ml of one of the standard solutions 1 to 5 and control solution on each plate. Put control solution in one cylinder on each plate and fill the remaining cylinders as follows. 1) Plate 1 has one control and three cylinders of solution1. 2) Plate 2 has one control and three cylinders of solution 2. 3) Plate 3 has one control and three cylinders of solution 3. 4) Plate4 has one control and three cylinders of solution 4. 5) Plate 5 has one control and three cylinders of solution 5. 6) Plate 6 has one control and three cylinders of sample (1). 7) Plate 7 has one control and three cylinders of sample (2). Fourth, place all the test plates were in an incubator at 35°C and cultivate for twenty hours [36].

According to the USP (our collected samples) the endotoxin and sterility tests were applicable in both cefteriaxone (for injection) and gentamicin (injection) samples. For endotoxin test were performed in two ways one for gel-clot thecnique and another was chromogenic technique. In gel-clot technique, at first 5 ml pure water were injected into the Limulus Ambocyte Lysate (LAL) vial. For another 10 ml pure water were injected into the standard endotoxin which concentration 1000 EU/ml and then vortex.

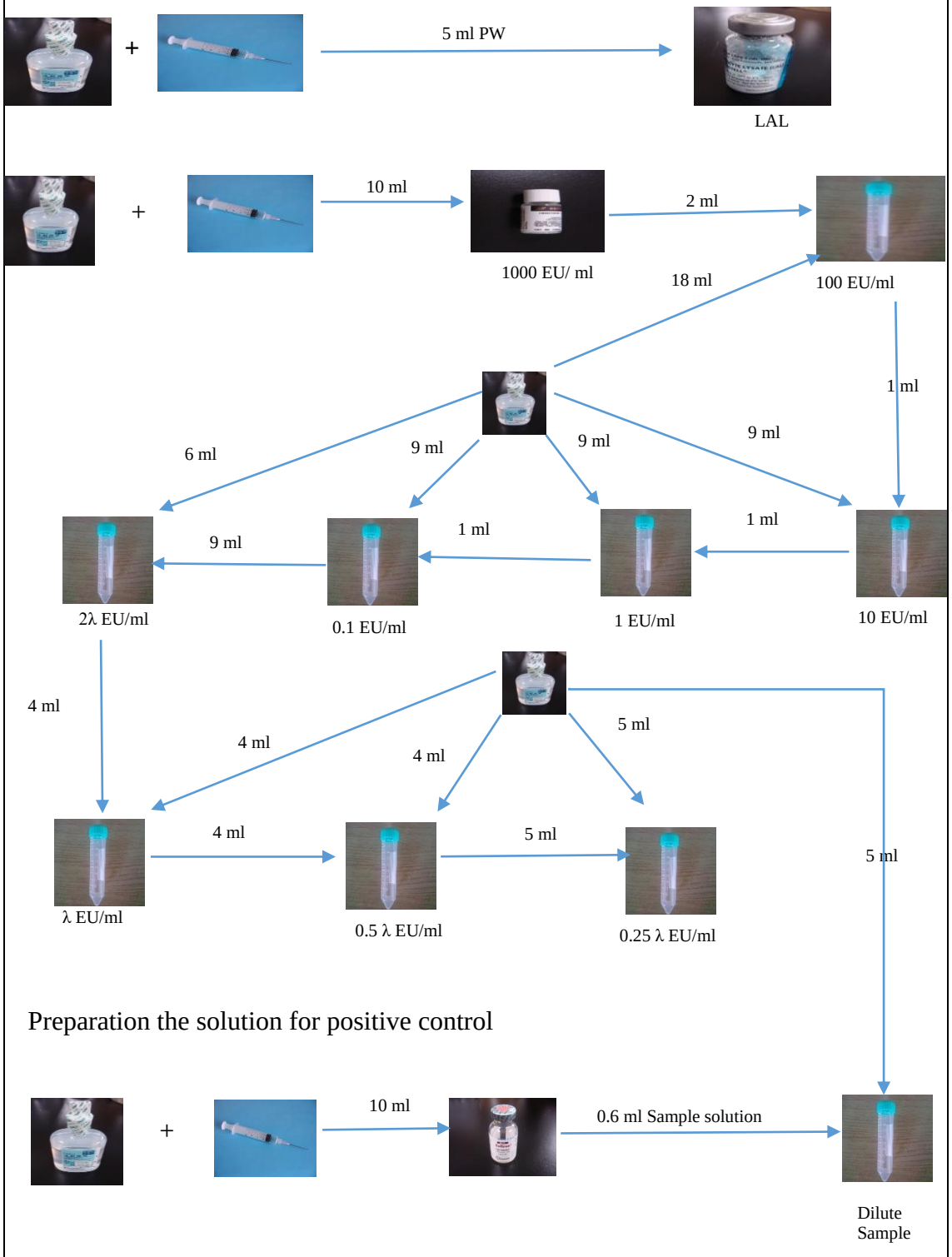
From this concentration to prepare 100, 10, 1, 0.1, 0.6 (2λ), 0.03 (λ), 0.015 (0.5λ) and 0.0075 (0.25λ) (Table 1.1). Each step was done for vortex in one minute and solutions were keep into an ice box. 10 ml pure water were used with sample and vortex for 1 minute, to make the sample solution. 0.6 ml were taken from the stoke solution with 5.4 ml pure water then vortex for 1 minute to make for dilute stoke solution. For the positive control, 1 ml from stoke solution with 1 ml from 100 EU/ml solution and then added 8 ml pure water to allow for vortex to make 10 EU/ml solution 1. 1 ml from the solution 1 with 9 ml pure water were used for 1 EU/ml solution 2. 0.3 ml solution 2 were taken and added 4.7 ml pure water for 2 λ solution 3. 1 ml from solution 3 with 7 ml of pure water were used to make 0.25 λ solution 4. A total 44 bottles were taken and transferred 0.1 ml of LAL reagent. Three bottles were used in each of the sample solution, positive control 10 EU/ml, standard endotoxin concentration 10 EU/ml and pure water as well as 1 battle was used for normal water. For an another case four bottle were used in each of the sample solution, positive control 10 EU/ml, 1 EU/ml, 2 λ and 0.25 λ. While two battles were used in each of the standard concentration 10 EU/ml, 1 EU/ml, 2 λ, 0.25 λ and pure water. After one an hour incubation and we observed about the positive control of 10 EU/ml and 1 EU/ ml, standard concentration 10 EU/ml and 1 EU/ml solution with normal water

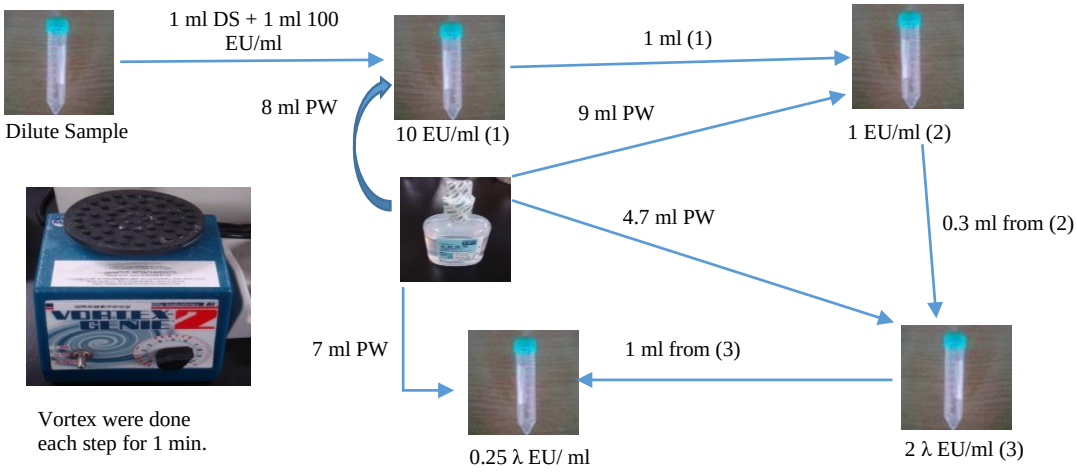
containing were solid in the bottles and rest of the bottles were liquid (Fig 1.3a & 1.3b) [37].

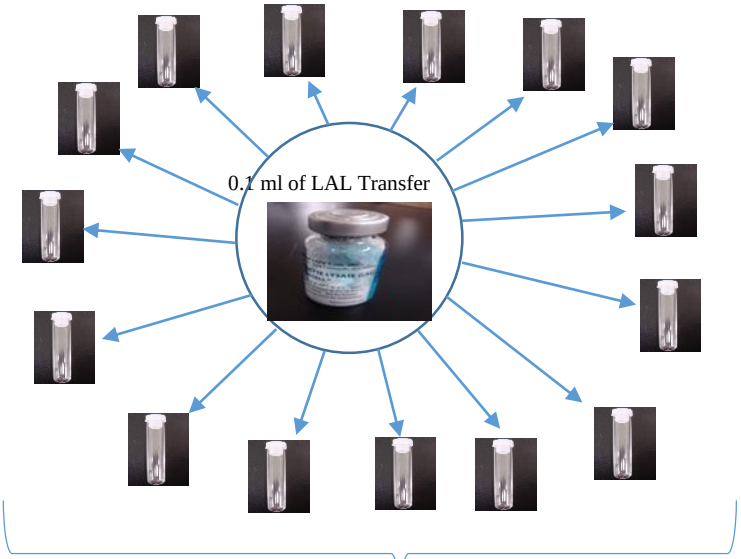
Table 1.1 Preparation of the different concentration of endotoxin solution

Concentration taken from the amount	Pure water	Concentration
From 1000 to 2 ml	18 ml	100
From 100 to 1 ml	9 ml	10
From 10 to 1 ml	9 ml	1
From 1 to 1 ml	9 ml	0.1
From 0.1 to 9 ml	6 ml	0.06 (2λ)
From 2 λ to 4 ml	4 ml	0.03 (λ)
From λ to 4 ml	4 ml	0.015 (0.5λ)
From 0.5 λ to 5 ml	5 ml	0.0075 (0.25λ)

Figure 1.3 Outline of endotoxin gel test







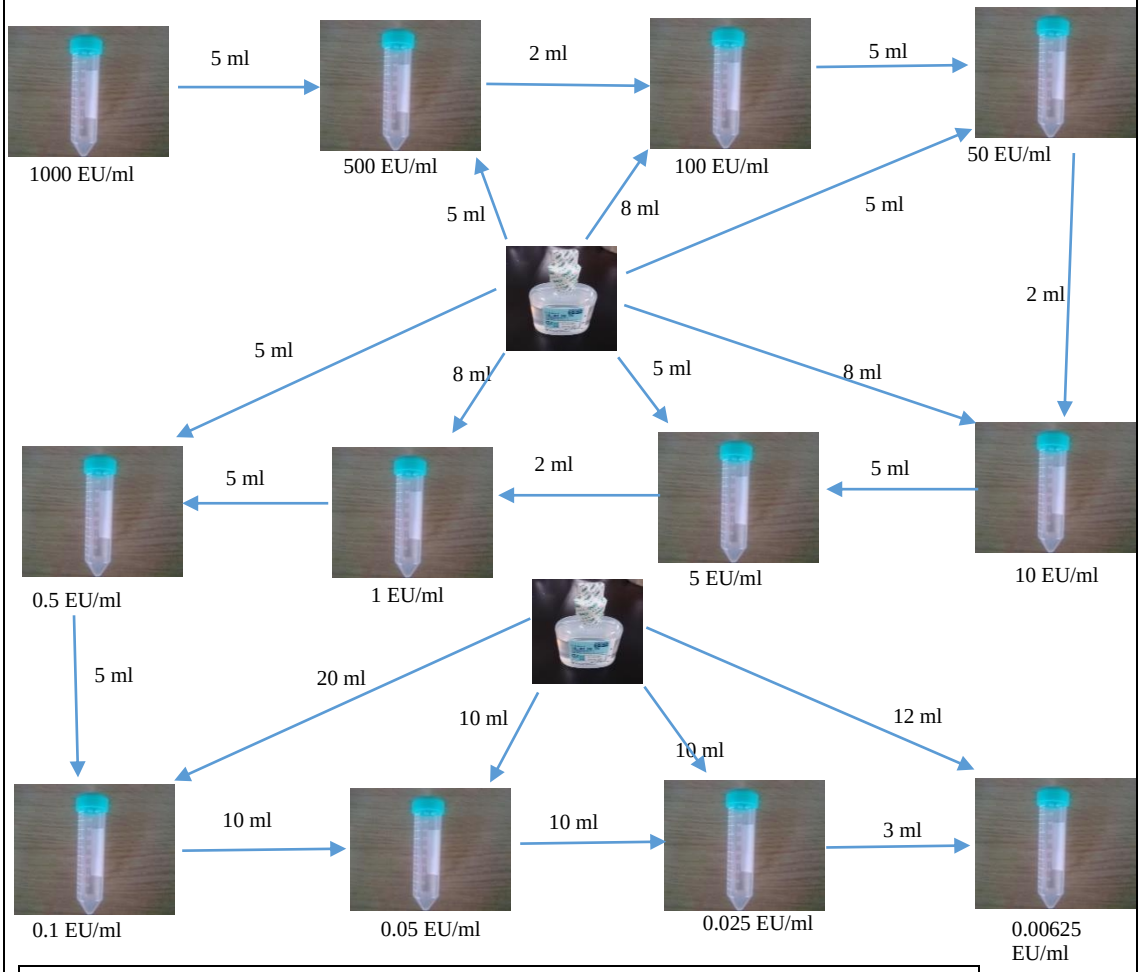
Incubation for 1 h

A total 44 bottles were taken. Three bottles were used in each of the sample solution, positive control 10 EU/ml, standard endotoxin concentration 10 EU/ml and pure water as well as 1 battle was used for normal water. For an another case four bottle were used in each of the sample solution, positive control 10 EU/ml, 1 EU/ml, 2 λ and 0.25 λ. While two battles were used in each of the standard concentration 10 EU/ml, 1 EU/ml, 2 λ, 0.25 λ and pure water. PW= Pure Water, DS= Dilute Sample

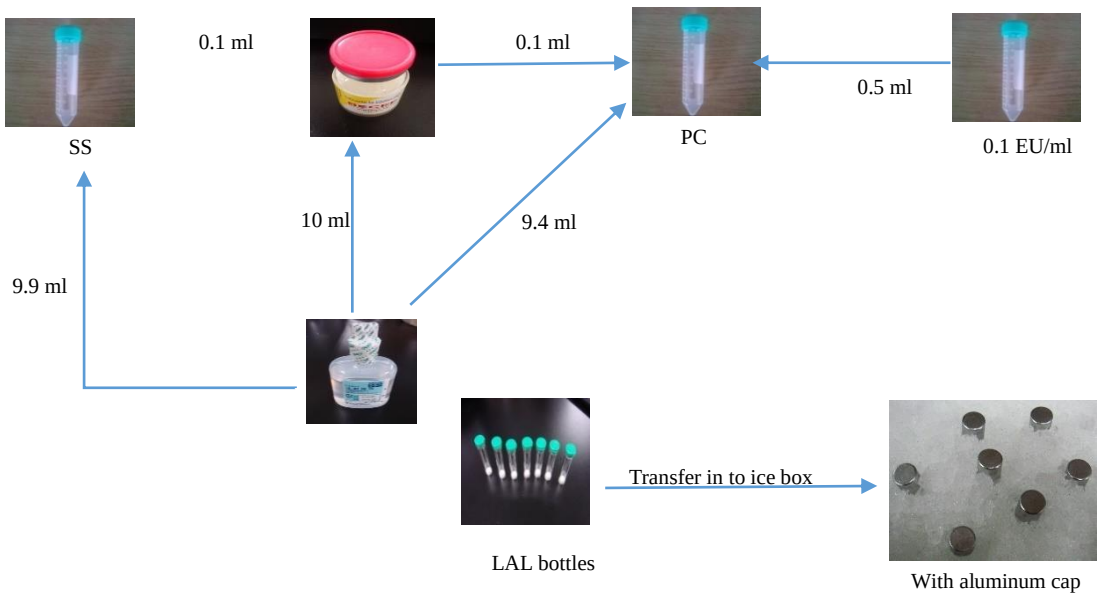
In colorimetric methods, 5 ml were taken from 1000 EU/ml and 5 ml PW were added to make the concentration 500 EU/ml then to prepare 100 EU/ml, 50 EU/ml, 10 EU/ml, 5 EU/ml, 1 EU/ml, 0.5 EU/ml, 0.1 EU/ml, 0.05 EU/ml, 0.025 EU/ml and 0.00625 EU/ml of the solution for calibration curve. 10 ml PW were injected into the sample for the sample stock solution (SS). For the making of sample solution, 0.1 ml were taken from the sample stock solution and added 9.9 ml PW were added as well as for the positive control of the solution, 0.1 ml taken from the stock solution and 0.5 ml were from standard concentration 0.1 EU/ml solution then 9.4 ml PW were added in a test tube. While PW were used as a negative control. 7 LAL bottles were taken and keep into the ice box with aluminum cap then marking for sample, positive control, negative control, standard concentration 0.1 EU/ml, 0.05 EU/ml, 0.025 EU/ml and 0.0065 EU/ml. 0.2 ml of buffer solution were added into each LAL battle (pipetting with no bubble). Each of 0.2 ml of the solutions sample, positive control, negative control, standard concentration 0.1 EU/ml, 0.05 EU/ml, 0.025 EU/ml and 0.0065 EU/ml were transferred into the representative LAL bottles and keep into the water bath for 30 minutes. During the bath preparation we were taken Pyrocolour MP which were containing 1, 1A, 2, 3, 3A kits. Just, solutions of the kit 1A were transferred into the kit 1 (sodium nitrite) as well as solutions of the kit 3A (N-Methyl- 2- pyrrolidone) were transferred into the kit 3 (N- (1-Napthyl) ethylenediamine

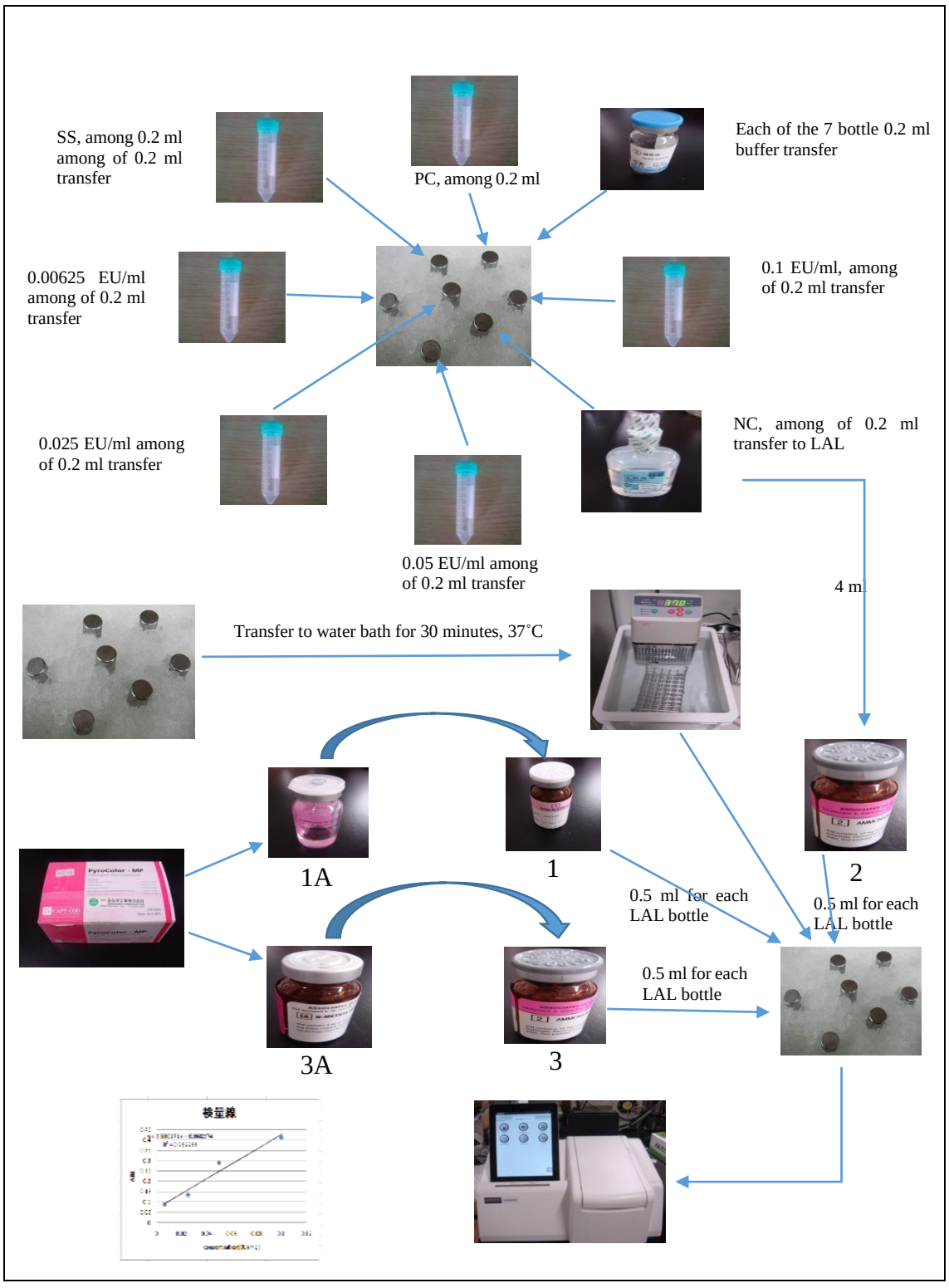
dihydrochloride). 4 ml Water were added into the kit 2 which containing Ammonium sulfamate. 7 LAL bottle were picked up from the water bath and put into the ice box. Each 0.5 ml solutions were taken from the prepared solutions 1, 2 and 3 and added of the seven bottles then allow for measuring spectrophotometer with 545 nm wavelength. After the measurement calculates the average concentration of endotoxin based on the calibration curve. Expected the absolute value of the correlation coefficient of the calibration curve is 0.98 or more (Figure 1.4a & 1.4b). Whether the measurement results of the water for injection (negative control) does not exceed the limit of the blank test, which is set in the lysate reagent, bellow the detection limit of endotoxin. For positive control and is based on the difference between the endotoxin concentration of the sample solution that, the recovery rate is calculated and it is in the range of 50% to 200% (Figure 1.4b). Based on the average endotoxin concentration of the sample solution to determine the endotoxin concentration of the sample, when meeting the endotoxin standards that value is defined, and pass the endotoxin test [38].

Figure 1.4 Outline of endotoxin test in colorimetric method



Preparation of sample solution (SS) and positive control solution (PC)




SS, among 0.2 ml among of 0.2 ml transfer
PC, among 0.2 ml
Each of the 7 bottle 0.2 ml buffer transfer
0.00625 EU/ml among of 0.2 ml transfer
0.1 EU/ml, among of 0.2 ml transfer
0.025 EU/ml among of 0.2 ml transfer
NC, among of 0.2 ml transfer to LAL
0.05 EU/ml among of 0.2 ml transfer
4 ml
Transfer to water bath for 30 minutes, 37˚C
1A
1
2
0.5 ml for each LAL bottle
0.5 ml for each LAL bottle
0.5 ml for each LAL bottle
3A
3

Regarding the sterility test were performed in both ceftriaxone and gentamicin samples. In this types of samples (injectable) must be contained in sterile condition. According to the pharmacopeia we were investigated on these types of samples. At first 10 ml pure water were injected into the samples. Steritest EZ Devices were clamped on the stand and tubes were properly griped in the Fluid Transfer Pump (FTP). Dehydration tubes were attached with the bottom side of the both kits. Fluid A were transferred into the both kits. Red caps were attached at the top side of the kites then the fluids were dehydrated by the using of dehydration tubes then red caps were leaved from the kites. Prepared samples were transferred in both kits and dehydration with red caps. Again fluid A were transferred into the both kits for washing and dehydration with red caps. The dehydration tubes and red caps were removed and yellow caps were attached with the bottom side of the kits. The tubes of the kits which were griped in the FTP, among one tube was blocked by the clip and other was open and tryptic soy broth medium transferred into the one kit. Similarly, other tube which was used to blocked and one tube opened, then fluid Thioglycollate medium were transferred to the kit. Both kits were picked from the stand. Tryptic soy broth medium containing kit was transferred an incubator which maintained at 21-25^{0}C as well as fluid Thioglycollate medium containing kit was transferred another incubator which was maintaining at 37^{0}C (Figure 1.5). Finally, we

observed both kits under 14 days for visible any particles, if the samples were contaminated by microorganisms [39].

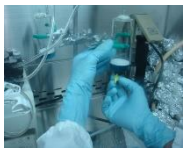
Figure 1.5 outline of sterility test

10 ml

Steritest EZ Devices were clamped on the stand and the tubes of Steritest EZ Devices were properly griped by the FTP

Dehydration tubes were attached bottom side of the kits and fluid A transfer into the both kits

Dehydration with red caps



At a time, sample were transferred into the both kits and dehydration with red caps

Again at a time fluid- A were transferred into the both kits for washing and dehydration with red caps

Dehydration tubes were rem-oved and attached yellow caps

One by one medium was transferred by one jar and another kit and allow for 21-25^{0}C and 37^{0}C incubator

1.4 Results:

1.4.1 Sample collection:

Outline of the samples collected in this study was summarized in Table 1.2. In our survey we collected 235 samples from 63 manufacturers with 71 different brand products. 14 (6%) samples were produced domestically. 49 (20.9%) Samples were ceftriaxone (1 gm/vial), 60 (25.5%) samples were cefuroxime (250 mg) [25], 58 (42.7%) samples were gentamicin (80 mg/ml) [27], 65 (27.7%) samples were omeprazole (20 mg) [26] and 3 (1.3%) samples were donepezil hydrochloride (5 mg) collected from Yangon, Myanmar.

1.4.2 Drug outlets and registration status in Myanmar FDA

We sampled 103 samples from community Pharmacy, 47 samples were governmental hospital, 42 samples were private hospital, 28 samples were clinic and 15 samples obtained from five different wholesalers as well as 6 (2.6%) samples were not registered in Myanmar FDA (Table 1.2).

Table 1.2 Outline of samples collection

Items	Government hospitals	Private hospitals	Community pharmacies	clinical pharmacies	wholesalers	No. of samples registered in Myanmar FDA	No. of samples unregistered in Myanmar FDA
Ceftriaxone(49)	9	11	18	7	4	49	0
Cefuroxime(60)	14	12	22	9	3	60	0
Donepezil Hydrochloride(3)	-	-	2	-	1	2	1
Gentamicin(58)	11	7	31	6	3	53	5
Omeprazole(65)	13	12	30	6	4	65	0
Total (235)	47 (20%)	42 (17.9%)	103 (43.8%)	28 (11.9%)	15 (6.4%)	229 (97.4%)	6 (2.6%)

1.4.3 Observations

In our observation 71 manufacturers were participated in this survey. While 8 manufacturers were repeated in more than one item of the medicines. We observed 41 manufacturers which were Indian originated (Figure 1.6). A total 235 samples were collected from Myanmar. Among of 149 samples out of 235 were found from Indian manufacturers (Figure 1.7). Mentioned on the label of each sample should be stored at ≤ 25-30°C with dry place. Only twenty-nine out of 74 retail shops (39.2%) are air-conditioning. 36 (15.5%) Out of 235 samples did not contain package inserts. We had collected two samples which did not found box (loos samples). While one sample of address was showing different in the label and insert. One cefuroxime sample of blister was torn in a hole and another manufacturer from Indian origin and their one sample was existed two different types of colour of the tablet in a strip. All ceftriaxone, cefuroxime and omeprazole samples were registered but one donepezil hydrochloride sample out of 3 (33 %) which was Indian origin and 5 gentamicin samples out of 58 (8.6 %) from two Chinese companies were not registered in Myanmar FDA (Table 1.3). 11 CXM and 2 GM samples were found which showing error spelling (Figure 1.8a & 1.8b). One GM sample was showing unequal volume with yellow colour (Figure 1.9).

Figure 1.6 Number of Manufacturers found in the program

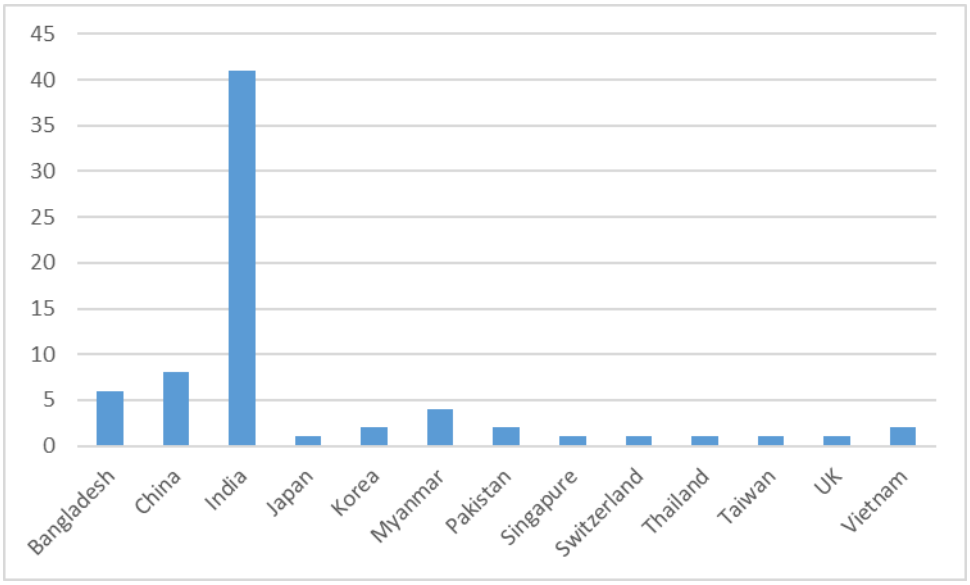


Figure 1.7 Number of samples collected from that origins

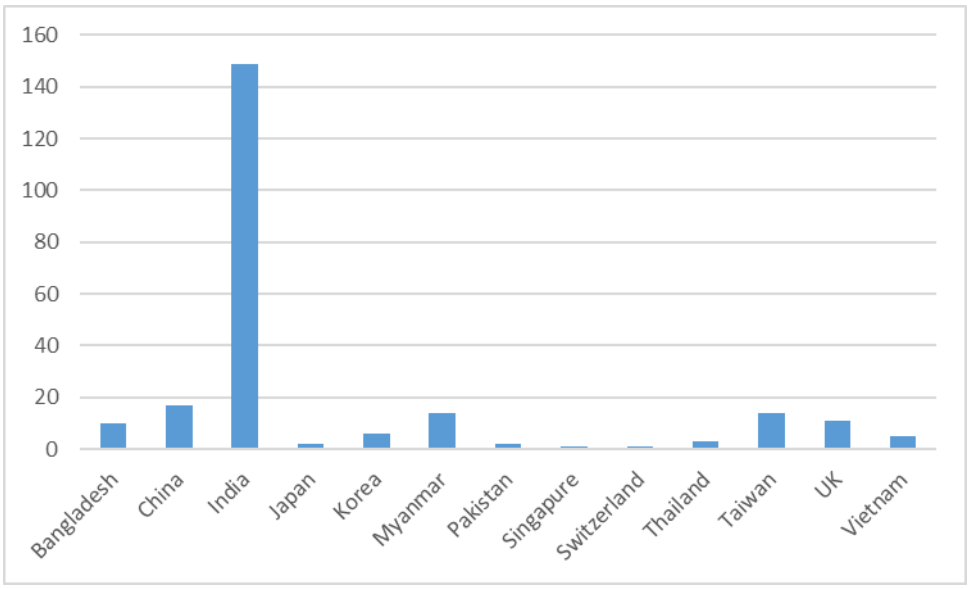


Figure 1.8a Spelling error in CXM samples A-030, 057, 068, 079, 085, 099, B-023, 047, 067, 093, 111

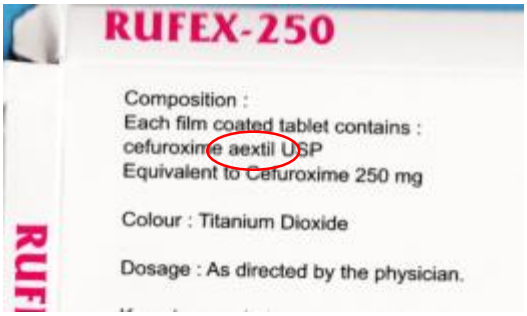


Figure 1.8b Spelling error in GM A-020 & A-077

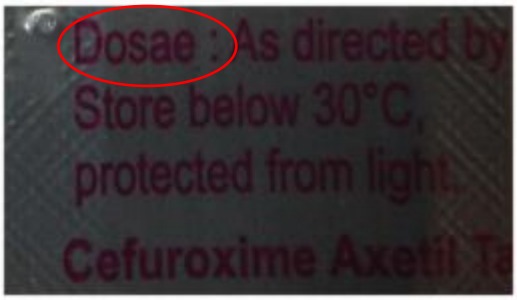
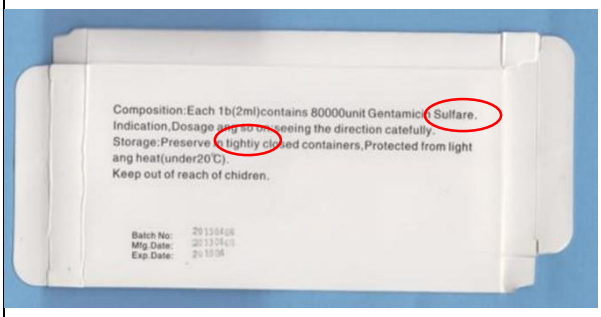


Figure 1.9 Low volume with different colour (yellow)



1.4.4 Authenticity

Authenticity investigation with the response from the manufacturers side were quite low. We received, 6 Manufacturers replied out of 19 that were represented of 8 samples out of 235 with agree as a genuine product (Table 1.3a & 1.3b), while 3 MRAs out of 12 MRAs in manufacturing countries informed about manufacturers licenses (Table 1.4). We obtained information from Myanmar, Switzerland and Bangladesh MRAs, but Bangladesh did not reply the questionnaire.

Table 1.3a Reply from manufacturers with their number of samples

Country	Manufacturer's name	Replied	Number of samples	Number of Brands	Reply on samples (N=235)		Authentic	
					Yes	No	Yes	No
Bangladesh	Aristo Pharma Ltd.	✓	2	1	0	0		
	Jayson Pharmaceutical Ltd.		1	1	0	0		
	Renata Limited		1	1	0	0		
	Square Pharmaceutical Ltd.		6	3	0	0		
	Subtotal		**10**	**6**	0	0		
China	Shenzhen Zhijun Pharmaceutical Co. Ltd		1	1	0	0		
	Beverly Henan Pharmaceutical Co. Ltd		1	1	0	0		
	Henan Dekang Pharma Actual Co; Ltd		2	1	0	0		
	Kunming Pharmaceutical Corp		2	1	0	0		
	Shanghai Modern Hasan Pharmaceutical Co. Ltd		2	1	0	0		
	Tianjin Pharmaceutical Group Xinzheng Co. Ltd		4	1	0	0		
	Zhanfeng Pharma. Factory, Long Chuan, Yunnan		4	1	0	0		
	河南龙源药业股份有限公司		1	1	0	0		
	Subtotal		**17**	**8**	0	0		
Japan	Eisai Co. Ltd	✓	2	1	0	0		
	Subtotal		**2**	**1**	0	0		
Korea	Korea Pharma Co. Ltd		2	1	0	0		
	Shin Poong Pharm. Co. Ltd		4	1	0	0		
	Subtotal		**6**	**2**	0	0		
Myanmar	Myanmar Pharmaceutical Factory		6	2	0	0		
	No.(1)Pharmaceutical Factory		2	1	0	0		
	No.(2) Pharmaceutical Factory		6	1	0	0		
	Subtotal		**14**	**4**	0	0		
Pakistan	CCL Pharmaceuticals(Pvt) Ltd.		2	2	0	0		
	Subtotal		**2**	**2**	0	0		
Singapore	Golden Kabaw Pte. Ltd		1	1	0	0		
	Subtotal		**1**	**1**	0	0		
Switzerland	F.Hoffmann-LaRoche Ltd.		1	1	0	0		
	Subtotal		**1**	**1**	0	0		
Taiwan	Siu Guan Chem, Ind. Co. Ltd		14	1	0	0		
	Subtotal		**14**	**1**	0	0		
Thailand	The United Drug Co., Ltd.		3	1	0	0		
	Subtotal		**3**	**1**	0	0		
UK	Glaxo Smith Kline		11	1	0	0		
	Subtotal		**11**	**1**	0	0		
Vietnam	Domesco Medical Import Export Joint Stock Corp		1	1	0	0		
	Fresenlus Kabi Bidiphar Jolnt - Stock Company	✓	3	1	3	0	3	
	Pharbaco Central Pharmaceuticals J.S.C No1		1	1	0	0		
	Subtotal		**5**	**3**	**3**	**0**	**3**	

Table 1.3b Reply from manufacturers with their number of samples

Country	Manufacturer's name	Replied	Number of samples	Number of Brands	Reply on samples (N=)		Authentic	
					Yes	No	Yes	No
India	Alkem Laboratories Ltd		20	1	0	0		
	AMN Life Science Pvt. Ltd		2	1	0	0		
	Asmoh Laboratories Ltd.		1	1	0	0		
	Belco Pharma		1	1	0	0		
	Blue Cross Laboratories Ltd		2	1	0	0		
	Brawn Laboratories Ltd		2	1	0	0		
	Cadila Health Limited		12	2	0	0		
	Cipla Ltd.		4	1	0	0		
	Dr. Reddy`s Laboratories Ltd		18	1	0	0		
	Eisai Pharmatechnology and Manufacturing Pvt	✓	1	1	1	0	1	
	Emcure Pharmaceuticals		4	2	0	0		
	Fourrts Laboratories Pvt. Ltd		2	1	0	0		
	Galpha Laboratories Ltd		2	1	0	0		
	Global Pharma Healthcare Pvt. Ltd		13	2	0	0		
	Great Himalayan Pte. Ltd		1	1	0	0		
	Intas Pharmaceuticals Ltd	✓	2	1	2	0	2	
	Lupin Ltd		5	2	0	0		
	Lyka Labs Limited		5	1	0	0		
	MDC Pharmaceuticals (P) Ltd		6	1	0	0		
	Mercury Laboratories Ltd		3	1	0	0		
	M. J. Biopharm Private Limited		2	1	0	0		
	Nectar Lifescience Ltd		8	1	0	0		
	Orchid Healthcare		4	1	0	0		
	Rainbow Life Sciences Pvt. Ltd		1	1	0	0		
	Ranbaxy Laboratories Limited		11	1	0	0		
	Regain Laboratories	✓	2	1	0	0		
	Rhydburg Pharmaceuticals Ltd		1	1	0	0		
	Saviour Pharmaceuticals		2	1	0	0		
	Stallina Laboratories Pvt. Ltd		1	1	0	0		
	SRS Pharmaceutical Pvt. Ltd		1	1	0	0		
	Toqure Pharmaceutical		1	1	0	0		
	Umedica Laboratories Ltd		3	1	0	0		
	Universal Pharmaceuticals Limited		1	1	0	0		
	Virchow Healthcare Private Limited		1	1	0	0		
	Wockhard Limited		2	1	0	0		
	XL Laboratories Pvt. Ltd.		2	1	0	0		
	Subtotal		**149**	**40**	**3**	**0**	**3**	

Table 1.4 Reply from MRAs

Country	Organization	Reply	Manufacturer		Sample	
			Legitimate	Non-approval suspected	Legitimate	Non-approval suspected
Bangladesh (n=4, 10 samples)	The Directorate General of Drug Administration Ministry of Health & Family Welfare	YES	uk	uk	uk	uk
China (n=8, 17 sample)	Department of Drug Registration State Food and Drug Administration, P.R. China the department of Drug & Cosmetics Registration	NO	-	-	-	-
India (n=36, 149 sample)	Drugs Controller General of India Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare New Delhi, India	NO	-	-	-	-
Korea (n=2, 6 sample)	Ministry of Food and Drug SAFETY	NO	-	-	-	-
Myanmar (n=3, 14)	Food Drug Administration of Myanmar	YES	3	0	14	0
Pakistan (n=1, 2 samples)	Director General Health| Drug Control Organization| Ministry of Health| Government of Pakistan	NO	-	-	-	-
Singapore (n=1, 1 samples)	Ministry of Health	NO	-	-	-	-
Switzerland (n=1, 1 samples)	Swiss medic (Swiss Agency for Therapeutic Products)	YES	1	0	1	0
Taiwan (n=1, 13 sample)	Food and Drug Administration (FDA)	NO	-	-	-	-
Thailand (n=1, 3 sample)	Food and Drug Administration	NO	-	-	-	-
United Kingdom (n=2, 11 sample)	MHRA	NO	-	-	-	-
Vietnam (n=3, 5 samples)	Cổngthông tin điệntửBộ Y tế (MOH)	NO	-	-	-	-

*We found two samples from a Japanese manufacturer. We confirmed about the license of the Japanese manufacture's from online.

1.4.5 Quality evaluate of samples

The results of the samples are showing in Annex 1.7 and Annex 1.8 as well as the summary of the results of quantity test is shown in Table 1.5. In the quality test 36 samples were unacceptable out of 177 samples. Among 176 samples were analyzed that finally confirmed, 27 samples were unacceptable in content uniformity tests as well as in the case for dissolution tests 23 samples were unacceptable out of 128 samples. In the case of omeprazole 23 (35.4%), 9 (13.8%) and 17 (26.2%) samples were unacceptable in quantity, content uniformity and dissolution test respectively [26]. In our investigation, we found 149 samples out of 235 from Indian origin. Among of the Indian 49 samples

were failed in any test out of 149 samples (Figure 1.10). Particularly, any fail of the all cefuroxime and omeprazole (except one from Bangladesh) samples came from India [25-26], while three counterfeit gentamicin samples were found from China (Figure 1.11, 1.12, 1.13, 1.14 & 1.15). We had collected 12 cefuroxime samples which manufacturer was Global Pharma Healthcare Pvt. Ltd, India. Among of them 10 samples were failed out of 12 [25]. Both endotoxin and sterility tests in ceftriaxone and gentamicin were satisfactory but in this case of unregistered three gentamicin samples out of 58 were failed in identification and during the analysis there were no peak appeared against standard solution at that moment (Fig. 1.16 & 1.17). While in the case of microbial assay test these three counterfeit gentamicin samples were not showing the zone of inhibition (Fig. 1.18). Myanmar Government announced three gentamicin samples from two Chinese manufacturers were counterfeited [27].

Table 1.5 Summary of quality test of samples

Items (n)	Assay test		Content uniformity test		Dissolution test		Endotoxin test		Sterility test		Identification		Microbial Assay	
	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail
Ceftriaxone (49)	47	2	46	3	-	-	49	0	49	0	49	0	-	-
Cefuroxime (60*)	49	11	44	15	54	6	-	-	-	-	60	0	-	-
Donepezil Hydrochloride (3)	3	0	3	0	3	0	-	-	-	-	3	0	-	-
Gentamicin (58)	-	-	-	-	-	-	58	0	58	0	55	3	55	3
Omeprazole (65)	42	23	56	9	48	17	-	-	-	-	65	0	-	-
Total (235)	141	36	149	27	105	23	107	0	107	0	232	3	55	3

*Result pending due to insufficient of samples

Figure 1.10 Comparison between pass and fail samples of origin

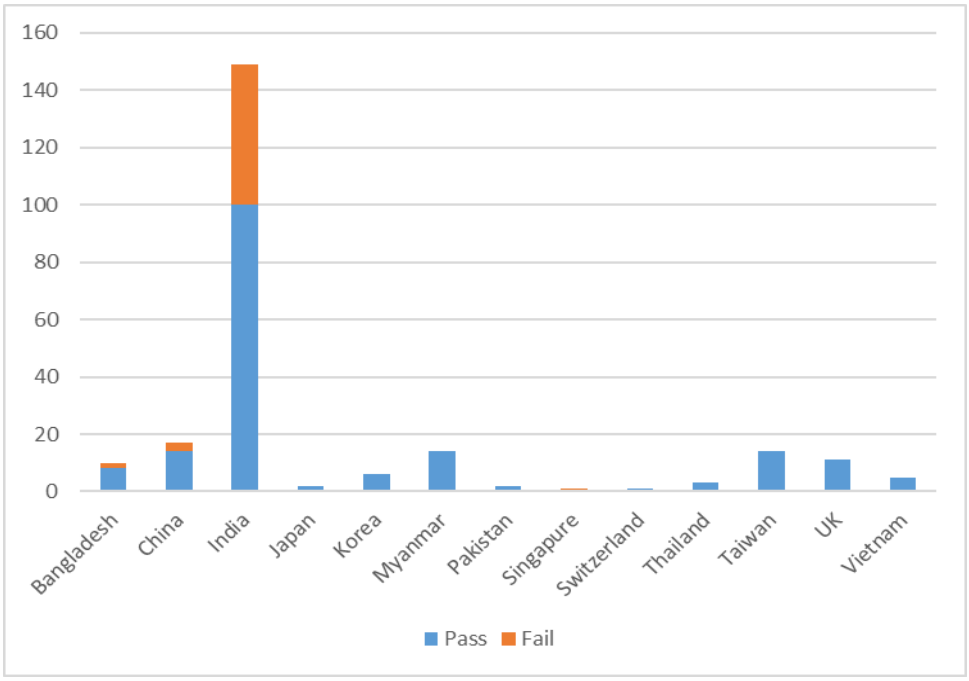


Figure 1.11 Comparison between CXM pass and fail samples of origin

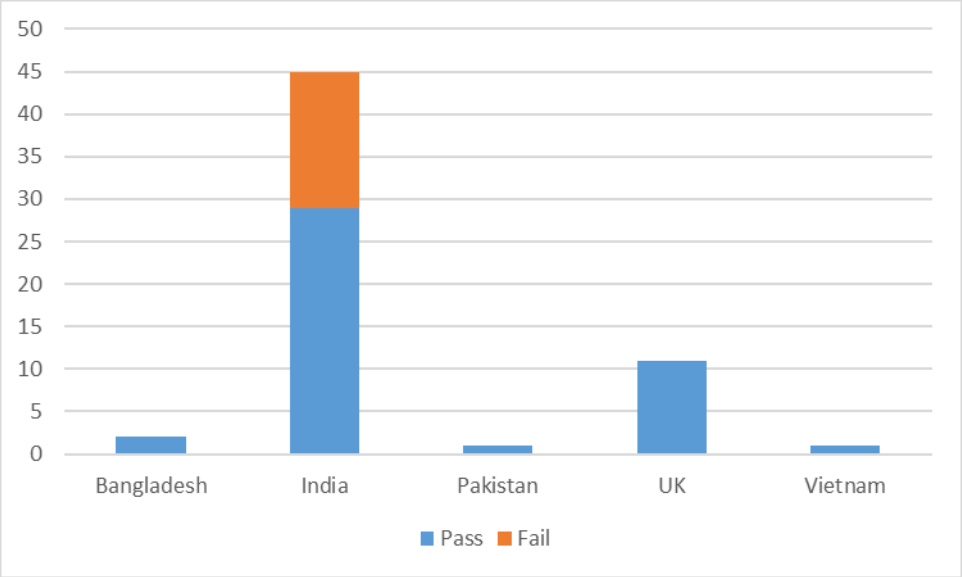


Figure 1.12 Comparison between OM pass and fail samples of origin

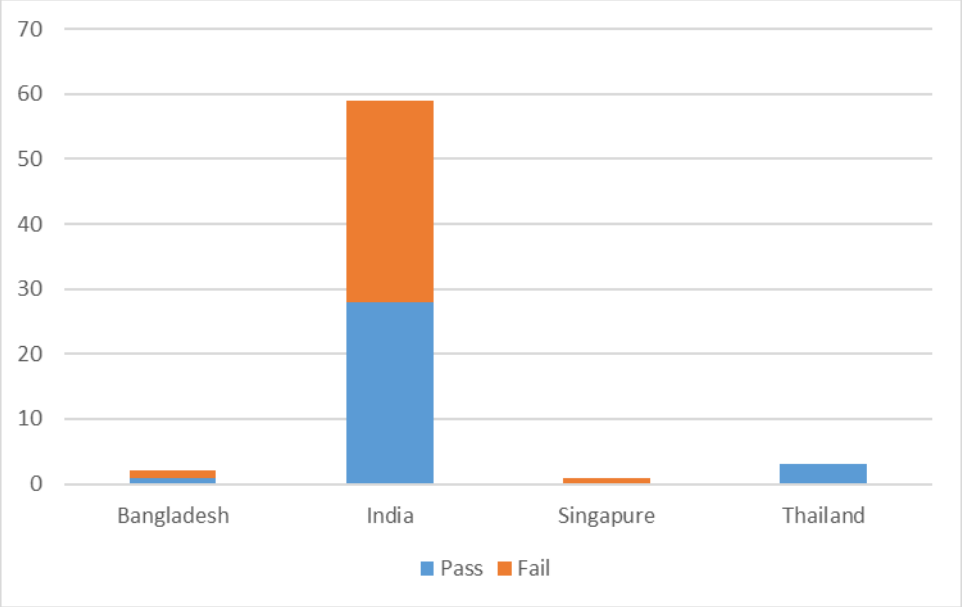


Figure 1.13 Comparison between GM pass and fail samples of origin

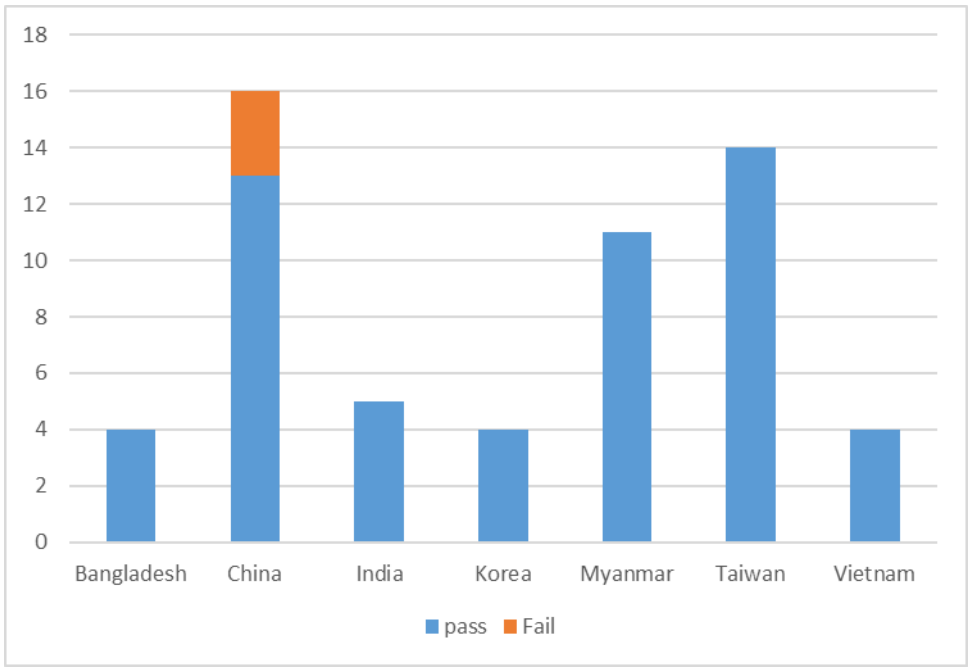


Figure 1.14 Comparison between CTRX pass and fail samples of origin

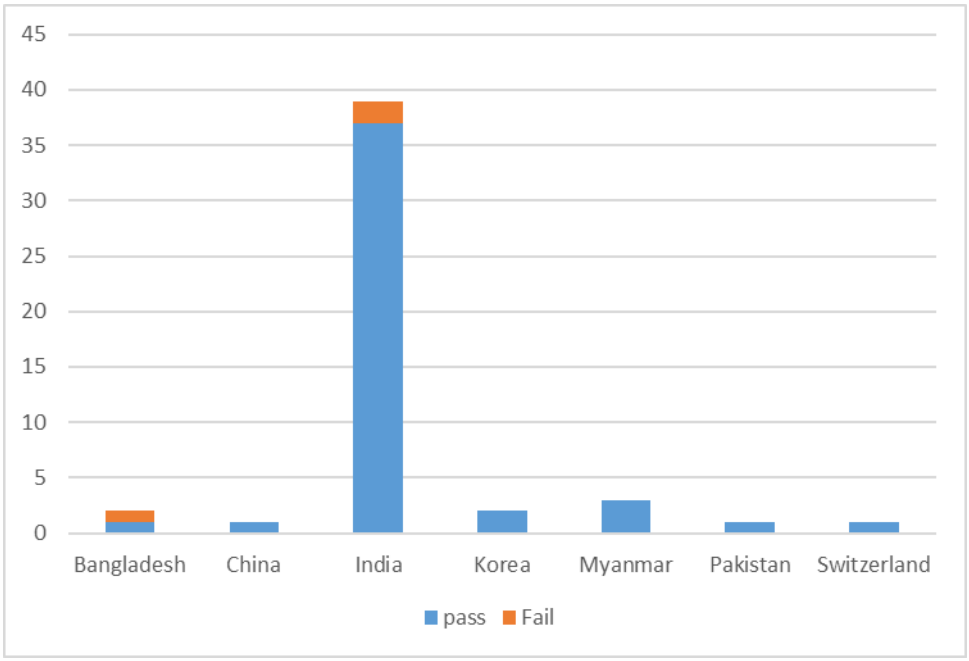


Figure 1.15 Comparison between DN pass and fail samples of origin

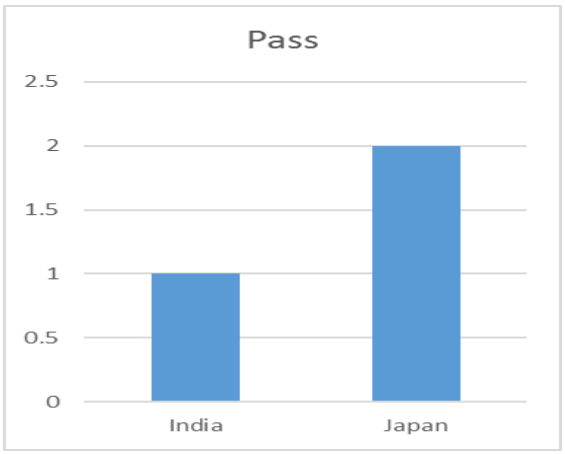


Figure 1.16 Chromatogram of GM standard

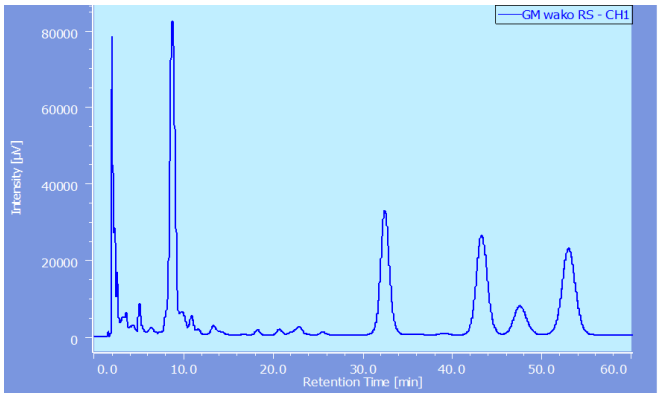


Figure 1.17 Chromatogram of counterfeit GM samples

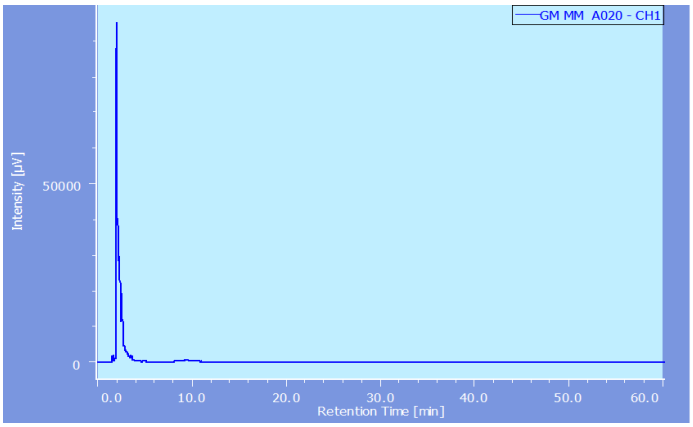
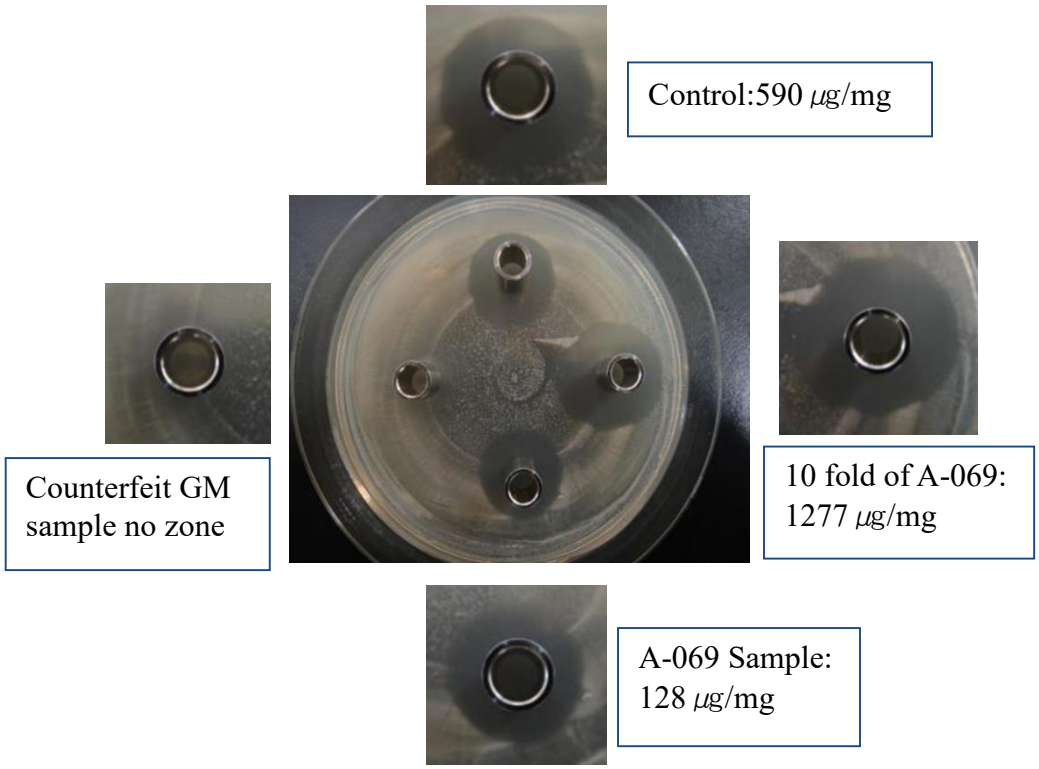


Figure 1.18 Counterfeit gentamicin samples

A-020 & A-077 A-069

Figure 1.19 Zone of inhibition (microbial assay) are showing between standard concentration and counterfeit GM samples



1.4.6 Factors influencing the outcome of the price

There was significant difference in the average price of passed and failed samples of cefuroxime (Student's *t*-test, $p<0.05$). In the samples of gentamicin, failed sample (identification, microbial assay) were significantly cheaper than passed samples (Student's *t*-test, $p<0.05$) and falsified ones were cheaper than other samples (Table 1.6).

1.4.7 Effect of air-conditioning

In the table 1.7, we also observed in significance that associated between air conditioning and temperature (*t*-test, $p<0.01$).

Table 1.6 Association between price and medical quality (CXM, GM, OM and CTRX)

		n	Mean(Kyat****) ±SD.	*p* (t-test)
CXM	all pass fail*	44 15	654.9± 206.7 374.8±122.6	P＜0.05
GM	Pass Fail**	55 3	145.1±73.0 38.3± 10.4	P＜0.05
OM	all pass fail*	32 32***	49.0±31.5 49.2±30.6	n.s.
CTRX	all pass fail	46 3	1634.1±1039.2 1650±650	n.s.

*Fail includes first, second and permanent fails.
** Counterfeit
**Excluded B-008 (free gift)
*** 1 Kyat ⇔0.00076$

Table 1.7 Association between air conditioning and temperature /humidity

Air-conditioning	n	Average temperature (℃) ±SD.	p (t-test)
yes no	29 44	28.6±2.6 30.8 ± 2.2	P＜0.01
		Average Humidity(%) ±SD.	
yes no	29 44	67.9 ± 12.4 69.3 ± 8.7	n.s.

1.4.8 To observe again of the unacceptable samples by using new judge which is wider than original (pharmacopeial criteria)

In Myanmar some samples were unacceptable, according to pharmacopeial test. We want to see, if the restricted value considers than original value how many samples are pass or fail. In dissolution test, we considered and calculated 80% of Q value of cefuroxime 75%, donepezil hydrochloride 80%, omeprazole 10% acid stage and 65% for buffer stage. For example, if Q value 75% so that, consider new value is 75*0.8= 60. In this case, the samples are containing ≤ 60 consider as a pass samples. In the case of content uniformity test the acceptance value (AV) is 15. In this case we consider 120%. Our new value is 15*1.2= 18. The samples which are containing AV bellow 18 consider as a pass samples in regarding this test. While quantity tests we multiply 0.8 with lower limit and upper value with 1.2 (80%-120%). The following tables 1.6 and 1.7 are showing the summary of comparisons between original and new value on pass and fail samples. While annex 1.8 are showing broadly of the results.

Table 1.8 Showing the comparisons of the pharmacopeial quality test between original and newly considered value.

Name of sample	DS original test		DS consider		QTY original		QTY consider		CU original		CU consider	
	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail
Cefuroxime(60*)	54	6	60	0	49	11	51	9	44	15	48	11
Omeprazole(65)	48	17	51	14	42	23	64	1	56	9	59	6
Ceftriaxone(49)	-	-	-	-	47	2	49	0	46	3	46	3

Table 1.9 are showing the comparisons between original all and new all tests.

Name of sample	Original all		New all	
	Pass	Fail	Pass	Fail
Cefuroxime(60)	44	16	49	11
Omeprazole(65)	33	32	45	20
Ceftriaxone(49)	46	3	46	3

Cefuroxime samples were analyzed in dissolution and 4 samples were finally failed. But when it was done 1st stage 12 sample were fail. To consider and apply new judge in cefuroxime samples (75*0.8= 60%) all sample pass in this test in first stage and need not to go for 2nd stage. Insert new judge for quantity test 80%-132% were considered. To apply new judge on 11 fail samples which were in 1st stage and all samples are pass in this stage and need not to go for 2nd stage in quantity test. In content uniformity to use new AV =18, 4 samples pass in this stage and need not to go for 2nd stage. Though all cefuroxime samples are not pass in content uniformity but we can say the results of dissolution and quantity test are satisfactory by using new judge.

In omeprazole samples in dissolution acid first stage to use new judge (12%) 2 fail samples and buffer stage (Q=57%) 18 samples pass in this stage and need not to go for 2nd stage. In the case of USP consider Q=65% pass 2 sample. In the same way when we judge in 2nd stage finally 14 samples are fail which were smaller than the original number. In quantity test all sample is pass except one when we use the new judge in 1st stage. In content uniformity 7 samples are fail when we use new judge that is lower than the actual number. In this case we can say quantity test of this samples are all most satisfactory but not in dissolution and content uniformity.

In ceftriaxone injection samples all samples are pass in quantity in 1st stage when use wider interval 72-138 and need not to go for 2nd stage. But in content uniformity test 3 fail samples are not changed if we apply new judge AV=18. Though all samples are not pass in CU but the result of quantity test are satisfactory. Summary of the results are showing in table 1.10 and broadly in annex 1.9.

Table 1.10 Compare the results between pharmacopeial guideline and considered new judge

Name of sample	Original all		New all	
	Pass	Fail	Pass	Fail
Cefuroxime (60)	44	16	49	11
Omeprazole (65)	33	32	45	20
Ceftriaxone (49)	46	3	46	3

***** Gentamicin three samples were failed in both identification and microbial assay which were not applicable for considered new judge, while all of Donepezil Hydrochloride were pass and need not to new judge.

1.4.9 Results of fluorescence spectrophotometer

We analyzed the excipient of gentamicin samples. We did not get any peak for samples of gentamicin and low peak observed of the samples which were showing in yellow colour of the samples as well as the samples which were pass found peak in the following figures.

Figure 1.20 counterfeit samples A-020 (China)

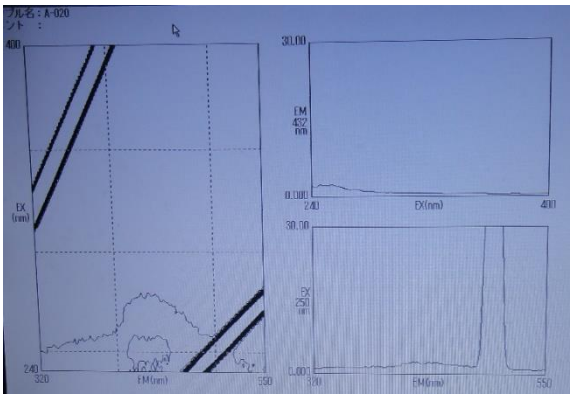


Figure 1.21 counterfeit sample A-069 (China)

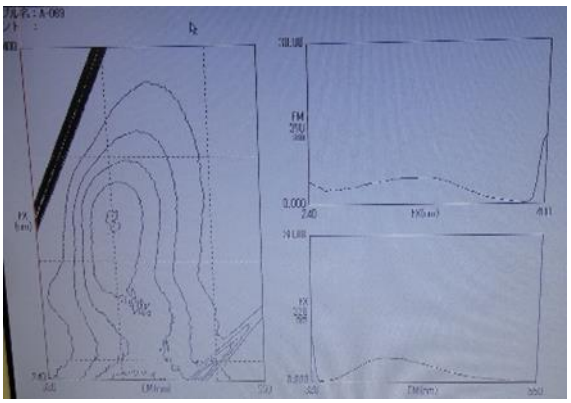


Figure 1.22 counterfeit sample A-077 (China)

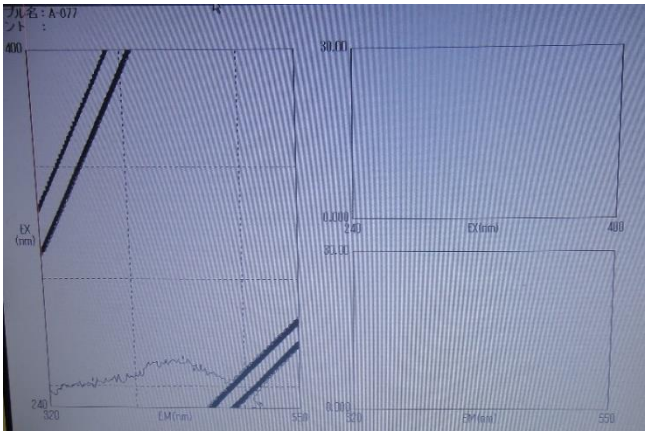


Figure 1.23 Pass sample B-09 (Bangladesh)

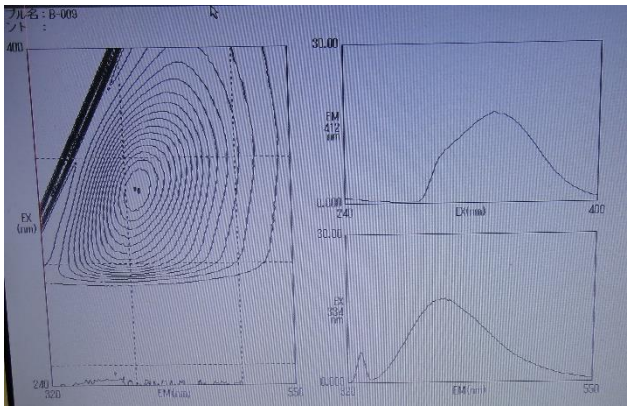
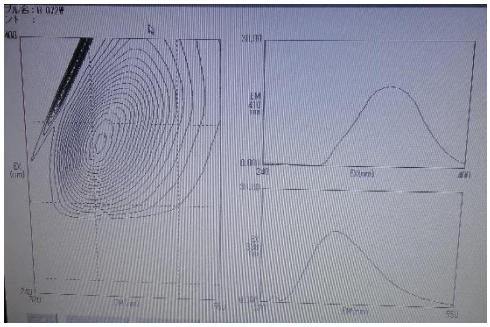
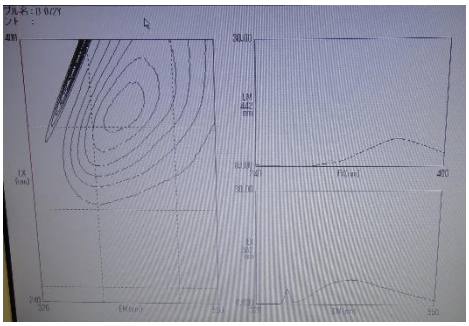


Figure 1.24 pass sample of B-072 but colour change white to yellow before the expiration (India)



White colour sample



Yellow colour

Figure 1.25 pass sample A-024 (Myanmar)

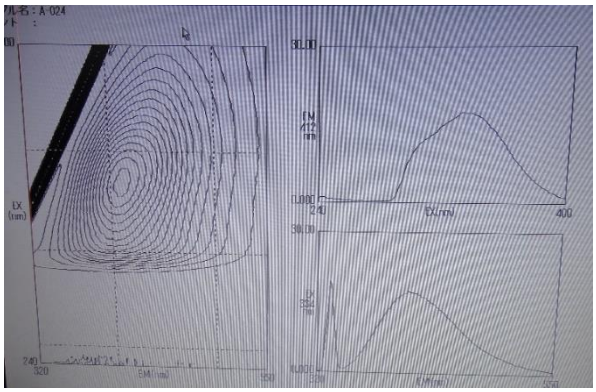


Figure 1.26 pass sample A-040 (Taiwan)

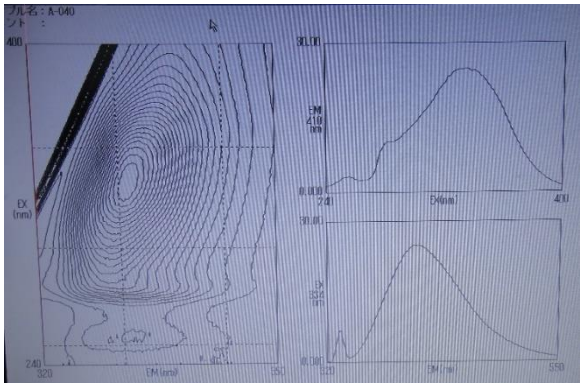
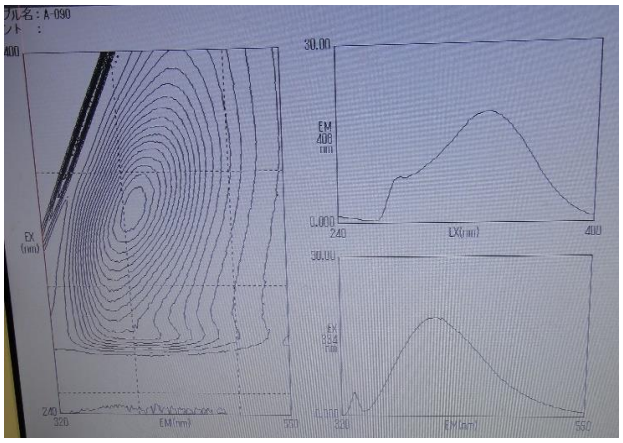


Figure 1.27 pass sample A-090 (Vietnam)



1.5 Discussion

We selected Yangon the commercial city of Myanmar, considered of population density and number of drug outlets. In this city, our survey and 235 samples were collected from pharmacy, governmental hospital, private hospital, clinic and also 15 (6.4%) samples were taken from wholesalers. Medicines must be stored at optimum temperature that mentioned on the label. Temperature is the most critical factors for degrading medicines not only in shop but also it can affect medicines during the distribution time [40-42]. Our all sampled medicines that mentioned on the label and should be keeping in ≤ 25-30°C with dry place, but air conditioner was set in fewer than half the number of retail shops visited. Under such situation in Myanmar good pharmacy practice, distribution practice and storage practice are not having satisfactory. Temperature and humidity parameters can be affected and decline the quality of product during the storage or distribution time. To obtain the better quality medicines it will be needed to develop the storage condition at the drug outlets. Most of the omeprazole samples were failed in quantity test as well as dissolution test. These products might be quality and eventually lead to adverse effect of health. This is similar to the high unacceptable ratio in dissolution of omeprazole samples collected in the Cambodian pharmaceutical markets [43].

Antibiotics have been prescribing against infectious diseases that are occurring by microorganisms. The roles of antibiotics in the world are able to kill or inhibit the growth of different types of infectious microorganisms and finally overcome from diseases by its proper uses. Unfortunately, misusing of antibiotic or counterfeiting from manufacturers end side that are increasing to resistance by microorganisms. Resistance to third generation cephalosporin series and aminoglycoside series have been established worldwide. Especially, resistance to third generation cephalosporin by Klebsiella pneumoniae and Neisseria gonorrhoeae were documented at 60% and 18% respectively in Myanmar [44, 45]. Sixty percent of Acinetobacter species, 60% of E. coli, 55% of Klebsiella species, 60% of Pseudomonas and 36 % of Staphlococcal species were resistance to gentamicin at North Okkalapa General Hospital in Myanmar [46]. Better qualities of antimicrobials drugs are key issue to prevent microbial resistance. We analyzed and observed in gentamicin samples but three samples out of 58 did not get the zone or low potency from the samples which were counterfeiting (Fig.1.19) as well as did not have peaks during the identification investigation (Fig. 1.17). In fluorescence spectrophotometer we farther investigate about the excipient of GM samples, we did not get any peak for the excipient during the investigation (Fig. 1.20-1.22). We found GM samples (injection) in vial which were low volume and some were yellow colour. During this investigation we observed the low peak for excipient which were yellow colour than

the white colour of the samples (Fig. 1.24). In our survey, we observed a strategy that was associated for spreading counterfeit samples. They made a plan and counterfeit samples were placed only to the community pharmacy. Though, we collected samples from community pharmacy, private hospital, government hospital and clinical pharmacy but the counterfeit samples of gentamicin that were collected from only community pharmacy and these counterfeit medicines produced by Chinese manufacturers who were not registered in Myanmar FDA. In the case of two nonregistered Chinese manufacturers were produced gentamicin, Myanmar government announced their products were counterfeited. Obviously it is compulsory to include antibiotic after any surgical operation to tackle infection from microorganisms.

In our studied, though analytical tests were satisfactory except five gentamicin samples while in the case of cefuroxime and ceftriaxone some samples were not satisfactory in pharmacopeias test. Even we observed one cefuroxime sample was showing torn in a hole of blister and another cefuroxime sample from Indian origin showing different colour in a same strip which were unexpected. Though ceftriaxone and gentamicin all samples were acceptable both sterility and endotoxin tests. Unacceptable cefuroxime tended to cost almost a half price of the pass products. Gentamicin belongs to the class of aminoglycoside antibiotics medicines which is killed or inhibits the growth of bacteria. The price of counterfeit gentamicin is one fourth cheaper than that of good-

quality products, even though no clear relation between unacceptable and price were observed in omeprazole and ceftriaxone products; we should be carefully to buy very cheap products compared to normal price of the domestic markets. Though the counterfeit medicines were very cheaper than the pass samples but other fail samples which were also cheaper as a poor quality not counterfeit. Thus, if cheaper medicines will import in future it must confirm the quality from manufacturers. Deliberately, the manufacturers were not only producing counterfeit medicines but also in manufacturing purpose they were using inexperienced manpower for more money saving. In this case we found spelling errors, different volume in the ampoule were not uniform of the solution (Fig. 1.8a, 1.8b & 1.9). Probably, this is the first report of counterfeit gentamicin in Myanmar. During the critical period the patients have been suffering these types of mistake and cannot separate from the authentic drugs. More overdue to lack of awareness general customers were confused these types of messages usually in the crucial time and entered to the danger zone. Spreading the drugs which are unregistered and distributed by unknown wholesaler or company is increasing the percentage of counterfeit to the markets. In this survey we found counterfeit gentamicin samples were unregistered in Myanmar FDA that above mentioned.

Investigation of this survey may not indicate the overall situation of Myanmar because we had several limitations like as region of sample collection, inadequate sample

size, random sampling and budgetary limitations. In authenticity investigation, we tried to communicate to the manufacturers and medicine regulatory authority of each country over telephone or by email which were involved in this program but, the response from the manufacturers side were quite low and there were no manufacturers to reply who were produced counterfeit drugs.

In Myanmar counterfeit medicines have been existing because survey was not conducted for long time. In our survey, we found counterfeit gentamicin which is a matter of serious concern, while chipper samples were more problematic than high price of the samples. For this reason, it is needed to evaluate the quality of medicines regularly in future. Any kind of medicine must be registered in country FDA with maintain actual protocol for storages and distribution time.

1.6 Conclusion

Counterfeit GM is being sold in Yangon. The quality of OM is a matter of concern, and requires follow-up. We found that a few specific manufacturers tend to produce poor-quality medicines. Regular surveys to monitor counterfeit and substandard medicines in Myanmar are recommended.

Chapter two

Four-year survey of the quality of antimicrobials in Cambodia

2.1 Introduction

Poor quality or falsified medicines are a serious problem which introduce the global issue especially in low-income countries from a public health point of view [4, 5, 47]. In particular, poor-quality antibiotics and antiparasitic agents may lead not only to treatment failure, but also to development of drug resistance [12,18,48,49,50]. For example, low concentrations of antibiotics accelerated the acquisition of resistance by *Salmonella typhimurium* LT2 strain, and the effect lasted for over 700 generations in vitro [51]. This problem is exacerbated by the use of antibiotics in the livestock sector as a growth promoter, with resistant strains being passed to humans [22]. The quality problem is not confined to antibiotics, however; in a study of 104 samples of anti-malarials in Southeast Asia in 2001, 38% were found to be substandard or falsified [52]. In Cambodia in 1999, substandard or falsified artesunate containing sulfadoxine-pyrimethamine caused the death of at least 30 people [53]. Falsified paracetamol that contained diethylene glycol killed more than 200 children in Bangladesh in 1990-1993 [17].

In Cambodia, the prevalence of falsified and substandard antibiotics has been reported to range from 4% to 90 %, according to the Ministry of Health and our earlier surveys [13-16, 43]. In this paper, we describe a 4-year consecutive investigation of medicines distributed in Cambodia, designed to investigate the quality of antimicrobial medicines in Cambodia, as well as to promote efforts to improve the quality of medicines on sale there in the future.

2.2 Objective

In Cambodia, the prevalence of falsified and substandard medicines has been reported to range from 4% to 90 %, according to the Ministry of Health and our earlier surveys. As a part of Cambodia's continuing efforts to eliminate falsified medicines, the

Ministry of Health of Cambodia in collaboration with Kanazawa University carried out a further survey designed to evaluate the quality of selected key medicines in the country as well as to promote efforts to improve the quality of both antimicrobial and lifesaving medicines on sale there in the future.

2.3 Materials and Methods

2.3.1 Selection of sampling areas

In consultation with the Department of Drugs and Food (DDF), Cambodia, we selected six sampling areas in the provinces of Battambang, Kandal, Kampong Speu and Takeo (rural areas) and in Phnom Penh, the capital of Cambodia (urban area) (Annex 2.1).

2.3.2 Sample collection

Samples of clarithromycin [54] and sulfamethoxazole/trimethoprim (June 2011) [55]; ceftriaxone (June 2012) [56]; cefuroxime [25], levofloxacin, gentamicin (August 2013) [57]; ciprofloxacin [58], fluconazole, nalidixic acid, ofloxacin, phenoxymethyl penicillin and roxithromycin (August2014) [59] were collected by two teams, each containing one or two Japanese researcher(s), one local assistant and one supervisor from DDF. Samples were collected from pharmacies, Depot-A, Depot-B, non-licenced drug outlets and wholesalers. Depot-A was defined as a site having a pharmacist with at least three years' pharmacy training, while Depot-B was defined as a site having a doctor or retired nurse in attendance.

2.3.3 Observation

The obtained samples were checked with reference to "Tool for Visual Inspection of Medicines" [28]. Packages, tablets and blisters of collected samples were observed

carefully for package data, packaging condition, Cambodian registration number on the label, and insert of each sample. Photographs were taken of each sample. During sampling, we also observed the environment of the drug outlets.

2.3.4 Authenticity

Authenticity investigation and registration verification were adopted from the World Health Organization procedures [16, 18, 48, 60, 61]. E-mail, contact address and telephone numbers were collected from each manufacturer with Medicine Regulatory Authority (MRA) from their web site. We sent photographs of samples with short questionnaires to the manufacturers to check authenticity and asked MRAs whether manufacturers were licensed or not. We also asked the DDF about sample registration in Cambodia.

2.3.5 Sample chemical analysis

The quality of samples was evaluated according to the pharmacopeia indicated on the sample package. For the quantity test, an HPLC method was adopted. A Shim-pack CLC-ODS (M) 15 cm column (Shimadzu, Kyoto, Japan) was used for clarithromycin, ceftriaxone, ciprofloxacin, fluconazole, nalidixic acid, ofloxacin, roxithromycin and gentamicin samples. A Shim-pack CLC-ODS (M) 25 cm column (Shimadzu, Kyoto, Japan) column was used for cefuroxime and levofloxacin samples, while a 30 cm column was used for sulfamethoxazole/trimethoprim samples. An NTR-VS6P dissolution tester (Toyama, Osaka, Japan) was used in dissolution test for all samples except in the cases of ceftriaxone for injection and gentamicin injection. All tests followed on pharmacopeial (according to the package information).

Table 2.1 HPLC conditions for pharmacopoeial tests

Items	Brand name of HPLC system	Column size	Wave-length	Oven temperature	AV≦	Quantity %	Q value for 30 min. in dissolution
Clarithromycin	Hitachi, Japan	4.6 mmX15 cm	210 nm	50˚C	15	90-110	≥80%
Sulfamethoxazole/ Trimethoprim	Shimadzu, Japan	4.6 mmX30 cm	254 nm	40˚C	15	90-110	≥70%
Levofloxacin	Shimadzu, Japan	4.6 mmX25 cm	260 nm	45˚C	15	90-110	≥75%
Ciprofloxacin	Waters, USA	4.6 mmX15 cm	278 nm	30˚C	15	90-110	≥75%
Fluconazole	Shimadzu, Japan	3.9 mmX15 cm	261 nm	40˚C	15	90-110	≥75%
Nalidixic Acid	Shimadzu, Japan	4.6 mmX15 cm	254 nm	25˚C	15	90-110	≥80%
Ofloxacin	Waters, USA	4.6 mmX15 cm	294 nm	25˚C	15	90-110	≥80%
Phenoxymethyl-penicillin	Shimadzu, Japan	4.6 mmX25 cm	254 nm	50˚C	-	90-120	≥75% (45min.)
Roxithromycin	Shimadzu, Japan	4.6 mmX15 cm	205 nm	30˚C	15	90-110	≥75%

*Ceftriaxone and gentamicin samples were analyzed previous way.

2.3.6 Statistical analysis

Data analysis was performed using SPSS 19.0.0 (SPSS Inc, Chicago, IL, USA). Student's t-test was used to determine the significance of differences in scale data. Statistical significance was assessed at 5% level.

2.4 Results

Collected samples are summarized in table 2.2. During the four-year survey, we collected 647 samples, produced by 179 manufacturers, involving 247 different brand products: 50 clarithromycin (n=24 500 mg, n=26 250 mg tablet) (7.7%) [54], 72 sulfamethoxazole/trimethoprim (n=24 800/160 mg, n=48 400/80 mg tablet) (11.1%) [55], 61 ceftriaxone (1gm vial) (9.4%) [56], 53 cefuroxime (250 mg tablet) (8.2%) [25], 60 levofloxacin (n=53 500 mg, n=7 250 mg tablet) (9.3%), 59 gentamicin (n=51 80 mg/2 ml ampoule, n=8 80 mg/2 ml vial) (9.1%) [57], 56 ciprofloxacin (500 mg tablets) (8.7%) [58], 57 fluconazole (n=5 150 mg, n=52 150 mg capsule) (8.8%), 9 nalidixic acid (n=3 1000 mg, n=6 500 mg tablet) (1.4%), 57 ofloxacin (200 mg tablet) (8.8%), 56 phenoxymethyl penicillin (n=13 250 mg, n=18 1000000 IU, n=6 400000 IU, n=19 500000 IU tablet) (8.7%) and 57 roxithromycin (150 mg tablet) (8.8%) samples [59], from Battambang, Kandal, Kampong Speu, Takeo and Phnom Penh. In these surveys we collected 390 (60.3%) samples from urban areas and the rest (257, 39.7%) from rural areas. We found that 138 (21.3%) of 647 samples were domestically produced by 28 (15.6%) manufacturers among the total of 179 manufacturers (Table 2.3).

2.4.1 Drug outlets

We collected 371 (57.3%) samples from pharmacies, 86 (13.3%) from Depot-A, 142 (21.9%) from Depot-B, 45 (7%) from wholesalers and 3 (0.5%) from non-licensed drug outlets (Table 2.1). There was no significance association among of these outlets in the quality test of pass and fail samples (Table 2.4).

Table 2.2 Outline of samples collection in Cambodia

Year	Antibiotic	No. of samples	Types of area		Type of drug outlet					Price/unit ($) mean ± SD
			Urban area no. of sample%	Rural area no. of sample%	Pharmacy no. of sample%	Depot-A no. of sample%	Depot-B no. of sample%	Wholesaler no. of sample%	non-licensed no. of sample%	
2011	Clarithromycin	50	28 (56%)	22(44%)	26 (52%)	5 (10%)	17 (34%)	2 (4%)	-	0.321 ± 0.198
	Sulfamethoxazole/ Trimethoprim	72	42 (58%)	30 (32%)	23 (32%)	15 (21%)	29 (40%)	4 (5%)	1 (2%)	0.039 ± 0.029
2012	Ceftriaxone	61	32 (52%)	29 (48%)	26 (43%)	10 (16%)	19 (31%)	4 (7%)	2 (3%)	1.086 ± 1.386
2013	Cefuroxime	53	37 (70%)	16 (30%)	34 (64%)	3 (6%)	10 (19%)	6 (11%)	-	0.468 ± 0.198
	Levofloxacin	60	35 (58%)	25 (32%)	30 (50%)	6 (10%)	18 (30%)	6 (10%)	-	0.384 ± 0.294
	Gentamicin	59	35 (59%)	24 (31%)	26 (44%)	11 (19%)	17 (29%)	5 (8%)	-	0.069 ± 0.032
2014	Ciprofloxacin	56	36 (64%)	20 (36%)	40 (71%)	7 (13%)	5 (9%)	4 (7%)	-	0.075 ± 0.120
	Fluconazole	57	35 (61%)	22 (29%)	36 (63%)	4 (7%)	9 (16%)	8 (14%)	-	0.427 ± 0.312
	Nalidixic Acid	9	6 (66%)	3 (34%)	6 (66%)	2 (22%)	1 (2%)	-	-	0.102 ± 0.072
	Ofloxacin	57	33 (58%)	24 (32%)	41 (72%)	6 (10%)	9 (16%)	1 (2%)	-	0.078 ± 0.039
	Phenoxymethyl penicillin	56	33 (59%)	23 (31%)	42 (75%)	8 (15%)	3 (5%)	3 (5%)	-	0.063 ± 0.112
	Roxithromycin	57	38 (66%)	19 (34%)	41 (72%)	9 (16%)	5 (9%)	2 (3%)	-	0.091 ± 0.092
	Total	647 (100%)	390 (60%)	257 (40%)	371 (57%)	86 (13%)	142 (22%)	45 (7%)	3 (1%)	

Urban area: The capital of Cambodia (Phnom Penh)
Rural area: Other provinces (Battambang, Kandal, Kampong Speu and Takeo) which are located outsides of capital city
Depot-A: Depot-A outlet by an assistant pharmacist (who received 3 years' pharmacy training)
Depot-B: Depot-B outlet by a doctor or retired nurse

Table 2.3 Number of samples collected which were produced domestically (Cambodia) foreign samples

Name of sample	Number of Cambodian samples	Number of Cambodian manufacturers	Number of foreign samples	Number of foreign manufacturers
Clarithromycin	14	2	36	8
Sulfamethoxazole/ Trimethoprim	42	6	30	9
Ceftriaxone	0	0	61	17
Cefuroxime	0	0	53	15
Levofloxacin	0	0	60	19
Gentamicin	0	0	59	12
Ciprofloxacin	18	5	38	15
Fluconazole	10	1	47	16
Nalidixic Acid	6	1	3	3
Ofloxacin	14	6	43	15
Phenoxymethyl penicillin	24	3	32	3
Roxithromycin	10	4	47	19
Total	138	28	509	151

Table 2.4 Significance association among the drug outlets in quality test

Outlet	Number of samples	Quality test		p (Fisher's exact test)
		Pass	Fail	
Pharmacy	371	269	102	n.s
Depot-A	86	64	22	
Depot-B	142	94	48	
Wholesaler	45	36	9	
Non-licensed	3	2	1	*

*Due to few samples not calculated in statistically

2.4.2 Observations

During the collection of samples, we observed that 51 shops out of 353 were air-conditioned. 85 (13.1%) samples lacked an insert, while insert information of one sample which was found in the package and package information about the medicine was not match during the observation. Five samples showed variations of package colour. Two lots of tablets and one ampoule showed different colours from others of the same brands. The blister which was picked from the package and it`s information did not match the package (which carry blister) information for one sample (Table 2.5). We collected 12 (1.9%) samples that were not registered with the DDF (Table 2.6). We found one cefuroxime sample that was a physician sample (this was mentioned on the box) [25], and one sulfamethoxazole/trimethoprim sample that had passed its expiration date [55].

Table 2.5 Number of abnormal samples were found during observation analysis.

Name of samples	Number of samples	Number of insert missing of the samples	Insert information not match to the package	Blister information did not match with container	Different package colour in same lot	Different colour of tablet/ ampoule
Clarithromycin	50	0	1	0	4	1
Sulfamethoxazole/ Trimethoprim	72	24	0	1	1	0
Ceftriaxone	61	2	0	0	0	0
Cefuroxime	53	2	0	0	0	0
Levofloxacin	60	0	0	0	0	0
Gentamicin	59	4	0	0	0	1
Ciprofloxacin	56	4	0	0	0	0
Fluconazole	57	4	0	0	0	0
Nalidixic Acid	9	3	0	0	0	0
Ofloxacin	57	8	0	0	0	0
Phenoxymethyl penicillin	56	32	0	0	0	0
Roxithromycin	57	2	0	0	0	0
Total	647	85 (13.1%)	1 (0.15%)	1 (0.15%)	5 (0.8%)	2 (0.30%)

Table 2.6 Number of unregistered samples in DDF

Name of medicine	Number of samples	Samples were unregistered in DDF
Clarithromycin	50	0
Sulfamethoxazole/ Trimethoprim	72	2
Ceftriaxone	61	2
Cefuroxime	53	2
Levofloxacin	60	0
Gentamicin	59	2
Ciprofloxacin	56	1
Fluconazole	57	0
Nalidixic Acid	9	3
Ofloxacin	57	0
Phenoxymethyl penicillin	56	0
Roxithromycin	57	0
Total	647	12 (1.9%)

2.4.3 Authenticity

In 2011, 11 manufacturers replied about 60 samples; in 2012, 4 manufacturers replied about 17 samples; in 2013, 15 manufacturers replied about 51 samples, and in 2014, 13 manufacturers replied about 26 samples, confirming that those samples were authentic. On the other hand, 18 MRAs out of 40 replied about manufacturer licenses and branded products (Table 2.7). The MRA in Germany replied that one manufacturer was not licensed.

2.4.4 Quality investigation of samples

The results of quality evaluation of collected samples are summarized in Table 2.8. In the quantity test, 533 (90.6%) out of 588 samples passed. Among 472 samples analyzed for content uniformity, 406 (86%) passed. In the dissolution test, 424 (80.4%) out of 527 samples passed. Identification, microbial assay, sterility and endotoxin tests were satisfactory. In the content uniformity test, the average price of failed samples of cefuroxime was significantly cheaper than that of passed samples (Student's t-test, $p<0.05$). In the dissolution test, failed samples of roxithromycin were significantly cheaper than passed samples (Table 2.9) (Student's t-test, $p<0.05$). In the dissolution test, there was a significant difference between the pass and fail rates of Cambodian-produced samples and foreign-produced samples (Table 2.10) (Fisher's exact test, $p<0.05$).

Table 2.7 MRAs and manufacturers replied during the authenticity investigation

Country	Participated year	MRAs replied year	Number of manufacturers participated	Number of samples	Number of manufacturers replied	Manufacturers confirmed all samples were genuine
Austria	2013 & 2014	20013& 2014	2	17	Not replied	-
Bangladesh	2011, 2012, 2013 & 2014	-	14	30	2 Replied in 2013	5
Cambodia	2011, 2014	2011 & 2014	16	128	16 in 2011	128
China	2013	2013	8	43	Not replied	-
Cyprus	2011, 2013 & 2014	2011	3	7	Not replied	-
France	2011 & 2014	2011	3	10	1 replied 2011	1
Germany	2013 & 2014	2011 & 2014	2	10	1 in 2013 & 1 I 2014	1
India	2011, 2012, 2013 & 2014	2011 & 2012	83	257	9 in 2013	-
Indonesia	2013 & 2014	-	4	5	1 in 2013	-
Korea	2011, 2014	2011	13	36	1 in 2011 & 1 in 2014	7
Malaysia	2011, 2013 & 2014	2011	3	10	1 in 2014	-
Pakistan	2011, 2012, 2013 & 2014	2011 & 2012	11	38	1 in 2011, 4 in 2012 & 1 in 2013	8
Singapore	2014	-	1	1	Not replied	-
Sweden	2012	2012	1	3	Replied	3
Thailand	2011, 2013 & 2014	2011	7	33	2 in 2011	1
United Kingdom	2013	2013	1	10	Not replied	-
Vietnam	2011, 2013 & 2014	-	7	9	Not replied	-

Table 2.8 Summary of quality test of samples

Antibiotic	Total no. of samples	Dissolution		Content uniformity		Quantity		Identification		Sterility		Endotoxin		Microbial assay	
		Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail
Clarithromycin	50	36	14	43	7	49	1	50	0	-	-	-	-	-	-
Sulfamethoxazole/ Trimethoprim	72	62	10	70	2	53	19	72	0	-	-	-	-	-	-
Ceftriaxone	61	-	-	46	15	48	13	61	0	61	0	61	0	-	-
Cefuroxime	53	53	0	43	10	51	2	53	0	-	-	-	-	-	-
Levofloxacin	60	42	18	-	-	57	3	60	0	-	-	-	-	-	-
Gentamicin	59	-	-	-	-	-	-	59	0	59	0	59	0	59	0
Ciprofloxacin	56	54	2	56	0	54	2	56	0	-	-	-	-	-	-
Fluconazole	57	29	28	40	17	54	3	57	0	-	-	-	-	-	-
Nalidixic Acid	9	3	6	9	0	9	0	9	0	-	-	-	-	-	-
Ofloxacin	57	49	8	44	13	46	11	57	0	-	-	-	-	-	-
Phenoxymethyl-penicillin	56	56	0	-	-	55	1	56	0	-	-	-	-	-	-
Roxithromycin	57	40	17	55	2	57	0	57	0	-	-	-	-	-	-
Total	647	424	103	406	66	533	55	647	0	120	0	120	0	59	0

Table 2.9 Comparison between price and result of the quality test in samples

Name of sample	Test	Result	Number of samples	Price/unit ($) mean ± SD	t-test
Clarithromycin	Dissolution	Pass	36	0.355±0.199	n.s
		Fail	14	0.235±0.174	
	Content uniformity	Pass	43	0.340±0.207	n.s
		Fail	7	0.209±0.159	
	Quantity	Pass	49	0.324±0.20	-
		Fail	1	0.20	
Sulfamethoxazole/ Trimethoprim	Dissolution	Pass	62	0.041±0.031	n.s
		Fail	10	0.028±0.011	
	Content uniformity	Pass	70	0.040±0.029	n.s
		Fail	2	0.42±0.14	
	Quantity	Pass	53	0.04±0.024	n.s
		Fail	19	0.038±0.407	
Ceftriaxone	Content uniformity	Pass	46	0.970±0.524	n.s
		Fail	15	0.661±0.339	
	Quantity	Pass	48	0.970±0.533	n.s
		Fail	13	0.69±0.360	
Cefuroxime	Dissolution	Pass	53	0.468±0.198	-
		Fail	0		
	Content uniformity	Pass	43	0.360±0.210	p<0.05
		Fail	10	0.510±0.180	
	Quantity	Pass	51	0.462±0.198	n.s
		Fail	2	0.615±0.190	
Levofloxacin	Dissolution	Pass	42	0.421±0.339	n.s
		Fail	18	0.303±0.228	
	Quantity	Pass	59	0.391±0.300	n.s
		Fail	3	0.247±0.024	
Gentamicin	All test	Pass	59	0.069±0.032	-
		Fail	0		
Ciprofloxacin	Dissolution	Pass	54	0.076±0.123	n.s
		Fail	2	0.049±0.016	
	Content uniformity	Pass	56	0.075±0.016	-
		Fail	0		
	Quantity	Pass	54	0.0758±0.123	n.s
		Fail	2	0.668±0.0102	
Fluconazole	Dissolution	Pass	29	0.448±0.348	n.s
		Fail	28	0.406±0.274	
	Content uniformity	Pass	40	0.419±0.319	n.s
		Fail	17	0.447±0.302	
	Quantity	Pass	54	0.426±0.317	n.s
		Fail	3	0.463±0.028	
Nalidixic Acid	Dissolution	Pass	3	0.088±0.0411	n.s
		Fail	6	0.109±0.086	
	Content uniformity	Pass	9	0.102±0.024	-
		Fail	0		
	Quantity	Pass	9	0.102±0.024	-
		Fail	0		
Ofloxacin	Dissolution	Pass	49	0.072±0.318	n.s
		Fail	8	0.118±0.502	
	Content uniformity	Pass	44	0.078±0.039	n.s
		Fail	13	0.079±0.038	
	Quantity	Pass	46	0.076±0.040	n.s
		Fail	11	0.88±0.034	
Phenoxymethyl-penicillin	Dissolution	Pass	56	0.063±0.112	-
		Fail	0		
	Quantity	Pass	55	0.064±0.113	-
		Fail	1	0.05	
Roxithromycin	Dissolution	Pass	40	0.0952±0.014	p<0.05
		Fail	17	0.082±0.022	
	Content uniformity	Pass	55	0.080±0.088	n.s
		Fail	2	0.785±0.048	
	Quantity	Pass	57	0.091±0.0921	-
		Fail	0		

Table 2.10 Factors associated with quality test found in roxithromycin samples which were originated from Cambodia and other countries

Factors		Manufactured Country	Number of samples	Test Result		*p* (Fisher's exact test)
				Pass	Fail	
Ciprofloxacin	Content uniformity	Cambodia	18	18	0	-
		other	38	38	0	
	Quantity	Cambodia	18	18	0	-
		other	38	36	2	
	Dissolution	Cambodia	18	18	0	-
		other	38	36	2	
Fluconazole	Content uniformity	Cambodia	10	7	3	n.s
		other	47	33	14	
	Quantity	Cambodia	10	10	0	-
		other	47	44	3	
	Dissolution	Cambodia	10	5	5	n.s
		other	47	24	23	
Nalidixic Acid	Content uniformity	Cambodia	6	6	0	-
		other	3	3	0	
	Quantity	Cambodia	6	6	0	-
		other	3	3	0	
	Dissolution	Cambodia	6	1	5	
		other	3	2	1	n.s
Ofloxacin	Content uniformity	Cambodia	13	11	2	n.s
		other	42	33	9	
	Quantity	Cambodia	13	11	2	n.s
		other	42	35	7	
	Dissolution	Cambodia	13	12	1	n.s
		other	42	37	5	
Phenoxymethyl penicillin	Quantity	Cambodia	24	23	1	-
		other	32	32	0	
	Dissolution	Cambodia	24	24	0	-
		other	32	32	0	
Roxithromycin	Content uniformity	Cambodia	10	10	0	-
		other	45	45	0	
	Quantity	Cambodia	10	10	0	-
		other	47	47	0	
	Dissolution	Cambodia	10	3	7	$p<0.05$
		other	47	37	10	
Clarithromycin	Content uniformity	Cambodia	14	12	2	
		other	36	31	5	
	Quantity	Cambodia	14	13	1	-
		other	36	36	0	
	Dissolution	Cambodia	14	9	5	n.s
		other	36	27	9	
Sulfamethoxazole/ Trimethoprim	Content uniformity	Cambodia	42	40	2	-
		other	30	30	0	
	Quantity	Cambodia	42	32	10	n.s
		other	30	21	9	
	Dissolution	Cambodia	42	36	6	n.s
		other	30	26	4	

2.5 Discussion

Falsified antibiotics have been found in previous surveys in Cambodia [43]. For this reason, our four-year survey covered a range of different regions in the country. Overall, we found that 424 (80.5%), 406 (86%), 533 (90.6%), 647 (100%), 120 (100%), 120 (100%) and 59 (100%) samples passed the dissolution, content uniformity, quantity, identification, sterility, endotoxin, and microbial assay tests respectively (Table 2.8). Thus, poor-quality medicines were still available in Cambodia during the study period. Possible reasons include poor GMP implementation by manufacturers and inadequate storage conditions in outlets in Cambodia. Only 51 of 353 outlets were air-conditioned. Cambodia is situated in a tropical region, and the summer season is hot and humid. Our statistical investigation we did not get significance association, the effect of temperature on pass or fail samples of medicines compare with those outlets containing air-conditioning. But it is well established that these conditions can markedly impair the quality of medicines [40-42]. In our investigation, failed samples were significantly cheaper than passed samples in the cases of cefuroxime and roxithromycin. Thus, it may be important to focus quality checks especially on cheaper medicines (Table 2.9). Foreign manufacturers not only supply poor quality medicines in the markets but also domestic manufactures were produced and supply this type of medicines to the markets. We found 10 roxithromycin products which were produced domestically. Significance was associated in number of pass and fail samples which compared with the foreign products (Table 2.10). We also found one expired sample, and this could present a health hazard to patients. About medicine indication information get from insert which must compulsory inside of box or container. We found 13.1% samples did not contain insert. Unregistered samples which may causes to increase poor quality medicines in the markets.

We found 1.9% samples were not registered in DDF (Table 2.6). In our investigation maximum unregistered samples did not pass according to their pharmacopoeial test.

Non-licenced drug outlets were found in Cambodia in previous studies [13, 16, 43, 60], but have since been almost completely closed down, and only permitted clinics continue to sell medicines, thanks to the vigorous efforts of the Cambodian government to strengthen pharmaceutical control (Table 2.2). But, our statistical analysis among of these outlets did not get any significance (Table 2.4)

More than 10% of the antibiotics sampled failed in various tests, except for levofloxacin, ciprofloxacin and phenoxymethyl penicillin (table 2.8). Among the failures, 28% of clarithromycin and 49.1% of fluconazole samples failed only in the dissolution test. On the other hand, 20% of ofloxacin and 26.4% of sulfamethoxazole/trimethoprim samples failed in content uniformity and quality tests, respectively. These results are unsatisfactory from the viewpoint of public health, and are also likely to promote bacterial resistance to antibiotics [12]. This is a serious issue, because it has been reported that 60% and 18% of *Klebsiella* pneumonia and *Neisseria* gonorrhea, respectively, have developed resistance even to third-generation cephalosporin [44, 45]. In North Okkalapa General Hospital in Myanmar, 60% of *Acinetobacter* species, 60% of *E. coli*, 55% of *Klebsiella*, 60% of *Pseudomonas* and 36% of *Staphylococcus* species were resistant to gentamicin [46]. In addition, resistance to old quinolones such as nalidixic acid, fluoroquinolones such as ciprofloxacin and ofloxacin, penicillins such as phenoxymethyl penicillin, macrolides such as roxithromycin and triazole antifungal drugs such as fluconazole has been documented globally. According to the 2014 WHO report, *E. coli* and *Shigella*

strains resistant to fluoroquinolones amounted to 31-32% and 11.8%, respectively, in Cambodia. *Streptococcus pneumoniae* resistant to penicillin has also been detected at a rate of 64% in Cambodia [45]. However, action against substandard or falsified medicines has improved the quality of medicines in recent years [13, 15,16]. In our four-year investigation we found poor-quality medicines, but we did not find any falsified medicines, which is consistent with the view that the quality of medicines in Cambodian markets has improved. The results of registration verification from DDF were also satisfactory.

The prevalence of poor-quality medicines found in our investigation is broadly consistent with that in other lower-income countries [62]. But, although no falsified medicine has been identified among the collected samples, it has not been possible to confirm the authenticity of all the samples.

2.6 Conclusion

Poor-quality antibiotics remained prevalent in Cambodia during 2011 to 2014. Efforts are needed to encourage manufacturers to follow GMP, and to ensure proper handling of medicines throughout the supply chain. Also, continuous monitoring of manufacturers' products by MRAs is needed to ensure all products are licensed.

Chapter three

Quality survey of selected medicines in Cambodia, 2011-2013

3.1 Introduction

Poor quality medicines are a serious issue for public health; for example, 200 children died in a Bangladesh hospital in 1990-93 after being given counterfeit paracetamol that had been substituted by diethylene glycol [17,19]. In 2016, the Supreme Court of Bangladesh ordered about twenty pharmaceutical companies identified as responsible for production of substandard drugs to cease operation [63]. Counterfeit medicines impact not only developing countries, but also high-income countries [64-68], although it has been estimated that 30% of counterfeit drugs are distributed in Africa, Asia, Middle East, compared with less than 1% in the USA and European countries [5, 69-71]. In addition to counterfeit medicines, substandard medicines are also an important issue; for example, in 1999 more than 30 people died after being given substandard sulfadoxine-pyrimethamine as an anti-malarial [53].

Since the 1990s, the Ministry of Health and law-enforcement agencies in Cambodia have been trying to identify and suppress the distribution of falsified medicines, in cooperation with various international organizations, including the World Health Organization (WHO), INTERPOL, USAID, US Pharmacopeial Convention (USP), and Japan Pharmaceutical Manufacturers Association (JPMA) [13, 60, 72-76]. Various surveys have found that the prevalence of counterfeit and substandard medicines in Cambodia ranged from 4% to 90% [13-16]. In a previous survey in 2010, we also found falsified and poor quality medicines in Cambodian markets [43, 62].

As a part of Cambodia's continuing efforts to eliminate falsified medicines, the Ministry of Health of Cambodia in collaboration with Kanazawa University carried out a further survey designed to evaluate the quality of selected key medicines in the country.

3.2 Methods

3.2.1 Sample collection

We decided to collect samples from regions of high population density, border regions and locations along national highways. In consultation with the Department of Drugs and Food (DDF), we selected Phnom Penh as an urban area, and Battambang, Kandal, Takeo, Kampong speu and Svay rieng as rural areas. A list of licensed drug outlets was obtained from DDF. The selected target drugs were cimetidine in 2011, amlodipine [77]; esomeprazole and rabeprazole [78] in 2012, glibenclamide [79] and metformin [80] in 2013. Samples were collected from four types of drug outlets: pharmacies, Depot-A, Depot-B and non-licensed drug outlets. Depot-A was defined as an outlet with a pharmacist who had at least 3 years' pharmacy training, and Depot-B was defined as an outlet that contained a doctor or retired nurse [81]. Some samples were also collected from wholesalers. Each of the two sampling teams contained a research investigator, a local officer who had received training, and a sampling assistant. A sampling form was used to record information about each sample at the time of purchase, and samples were keep 20-25°C until analyzed.

3.2.2 Observation

The condition of each package, the colour of the box, the appearance of the medicines, and the insert in each package were carefully examined at Kanazawa University, and compared with those of other samples of the same brand, and the logo on the box was compared with that on the labeled supplier's internet home page. The manufacturing date, expiry date, lot number, license number, and Cambodian registration

number were also recorded. Samples were photographed, and scans of the box and insert were made.

3.2.3 Authenticity

Authenticity investigation was conducted according to the recommendations of the World Health Organization (WHO) [16, 48]. Information on the label, photographs of samples, scans of the box and insert, and a short questionnaire were sent to manufacturers by E-mail, and manufacturers were also contacted by telephone using the number on their internet home page. We asked the responsible MRAs whether or not the manufacturers were registered. We also asked the DDF whether or not the collected medicines were registered in Cambodia.

3.2.4 Quality analysis

Sample quality was evaluated according to the Pharmacopeia stated on the label, using the USP 34, USP 35 and BP 2012 versions of the pharmacopeias [82-84]. Content uniformity tests were performed with 10 tablets/capsules of all samples. The HPLC columns and parameters used during the content uniformity tests are listed in Table 3.1. Quantity and dissolution tests followed the relevant pharmacopeial descriptions. Dissolution tests for all samples were performed with 6 tablets/capsules by using an NTR-VS6P dissolution tester (Toyama, Osaka, Japan).

3.2.5 Statistical analysis

Data analysis was performed using SPSS release 19.0.0 (Chicago: SPSS Inc.). When appropriate, Fisher's exact test was performed to identify significant relationships among variables. Statistical significance was evaluated at 5% level.

Table 3.1 HPLC conditions for pharmacopoeial tests

Items	Brand name of HPLC system	Column size	Wave-length	Oven temperature	AV≦	Quantity %	Q value for 30 min. in dissolution
Amlodipine	Hitachi, Japan	4.6 mmX15 cm	237 nm	40˚C	15	90-110	≥75%
Cimetidine	Shimadzu, Japan	4.6 mmX25 cm	220 nm	40˚C	15	90-110	≥80%
Esomeprazole	Shimadzu, Japan	4.0 mmX10cm	302 nm	30˚C	15	90-110	≥75%
Glibenclamide	Waters, USA	4.6 mmX15 cm	254 nm	25˚C	15	90-110	≥70%
Metformin	Shimadzu, Japan	4.6 mmX25 cm	218 nm	30˚C	15	90-110	≥70%
Rabeprazole	Waters, USA	4.6 mmX15 cm	290 nm	30˚C	15	90-110	≥75%

3.3 Results

As summarized in Table 3.2, we collected 86 (25.1%) samples of cimetidine (40 mg tablet), 79 (23.1%) amlodipine (n=3 10 mg capsule & n=76 5 mg tablet) [77], 54 (15.8%) esomeprazole (20 mg n=14 capsule & n=12 tablets; 40 mg tablet n=16 & n=12 capsule), 11 (3.2%) rabeprazole (10 mg n=1 capsule & 20 mg n=10 tablet) [78], 60 (17.5%) metformin (500 mg tablet) [80] and 52 (15.2%) glibenclamide (5 mg tablet) [79]. Most of the samples (223, 65.2%) were collected from Phnom Penh, and the others (119, 34.8%) were collected from rural areas.

3.3.1 Drug Outlets

We collected total 342 samples from 263 drug outlets in the investigated regions. We obtained 156 (45.6%) from pharmacies, 62 (18.1%) from Depot-A, 96 (28.1%) from Depot-B, and 30 (8.2%) from wholesalers (Table 3.2).

Table 3.2 Number of samples collected from different outlets

Year/Name of samples	No. of samples	Area		Type of drug outlet			
		Urban	Rural	Pharmacy	Depot-A	Depot-B	Wholesaler
2011							
Cimetidine	86	57	29	30	19	34	3
2012							
Amlodipine	79	45	34	33	12	27	7
Esomeprazole	54	38	16	28	4	13	9
Rabeprazole	11	10	1	8	0	2	1
2013							
Glibenclamide	52	33	19	25	14	10	3
Metformin	60	40	20	32	13	10	5
Total	342	223	119	156	62	96	28

3.3.2 Observations

Among 263 outlets, only 18 were air-conditioned. The samples originated from 78 manufacturers, and 38 (11.1%) were domestically produced. Three samples of cimetidine and one of amlodipine were in boxes or containers of nonstandard colour (Fig. 1a, 1b). The colour of the tablets in two different samples did not match among the samples of cimetidine and amlodipine (Fig. 1c). The inserts in the two samples did not match those in other samples of the same brand. In addition, 32 (9.4%) samples had no insert.

3.3.3 Authenticity

The DDF reported that 14 samples out of 342 were not registered (Table 3.3). Replies stating that products were authentic were received from 8 out of 27 manufacturers in 2011, 7 out of 35 manufacturers in 2012 and 6 out of 19 manufacturers in 2013. Thus, the response rate was quite poor. On the other hand, we received replies from 7 out of 12 MRAs in 2011, 7 out of 13 MRAs in 2012 and 2 out of 10 MRAs in 2013, stating that manufacturers were registered in their country.

Figure 3.1

a: Different boxes or containers of cimetidine.

a.

Different boxes or containers of cimetidine

b: Different colour of the box of amlodipine sample

Different boxes of amlodipine

c: Different tablets of amlodipine

Different tablets of cimetidine

Different tablets of amlodipine

Table 3.3 Samples without registration or insert

Items	Unregistered	No insert in box
Cimetidine	3	23
Amlodipine	7	3
Esomeprazole	1	2
Rabeprazole	0	0
Glibenclamide	1	1
Metformin	2	3
Total	14	32

3.3.4 Quality evaluation

The test results for the 342 samples are summarized in Table 3.4. We found that 38 (11.1%) samples failed the dissolution test, and 52 (15.2%) failed the content uniformity test. In addition, 48 (14%) samples out of 342 failed the quantity test. In the case of rabeprazole, 11 samples originated from Japan passed all the tests, whereas 16 (42.1%) samples out of 38 produced domestically failed in one or more tests. Failure rates in quality tests were significantly associated with anomalies in visual observation of the samples (Fisher`s exact test, $p<0.01$ & $p<0.05$) (Table 3.5).

Table 3.4 Summary of quality test of samples

Sample name	No. of samples	Dissolution		Content uniformity		Quantity	
		Pass	Fail	Pass	Fail	Pass	Fail
Cimetidine	86	79	7	65	21	71	15
Amlodipine	79	77	2	73	6	78	1
Esomeprazole	54*	31	22	32	22	33	21
Rabeprazole	11	11	0	11	0	11	0
Glibenclamide	52	47	5	49	3	46	6
Metformin	60	58	2	60	0	55	5
Total	342	303	38	290	52	294	48

* Sample size was insufficient for testing in some cases.

Table 3.5 Statistical analysis

						Fisher's exact test
		Content uniformity				
		Pass	Fail			
Cimetidine	Domestic	19	8			p<0.05
	Imported	49	6			
		Content uniformity				
		Pass	Fail			
Amlodipine	Phnom Penh	45	0			p<0.01
	Other	27	6			
				Price per unit ($)		
Esomeprazole	Dissolution	Pass	31	0.32 ± 0.08		p<0.05
		Fail	22	0.21 ± 0.11		
	Quantity	Pass	33	0.42 ± 0.12		p<0.05
		Fail	21	0.30 ± 0.11		
Both Glibenclamide and Metformin	Factors		No. of samples	Pharmacist		
				Absence	Presence	
	Air conditioning	Absence	100	67	33	p<0.05
		Presence	12	2	10	

3.5 Discussion

Cambodia lies in a tropical region, and is very hot and humid in the summer season. These factors can seriously impact on the quality of improperly stored medicines [40-42]. Among the outlets from which samples were collected, we found that all the wholesalers were equipped with air-conditioning, but very few other outlets had air-conditioning. There seems to be a clear need to improve the storage conditions in retail outlets in order to improve the quality of medicines.

We observed some samples of boxes that had been imported, but showed a different colour compared with other samples of the same brand. The fact that these were on sale suggests that customers were not necessarily familiar with the authentic products. On the other hand, printing technology makes it quite easy to prepare packages for falsified medicines that resemble authentic products [47, 85]. In our investigation we also found two samples of tablets that had nonstandard colours. Among samples from both foreign and domestic manufacturers, we found that 32 (9.4%) lacked sample inserts in the box, although it was not clear whether inserts had been omitted by the manufacturers or removed by retailers. Among 14 samples that had been imported but not registered with the DDF (Table 3.3), 4 (28.6%) failed pharmacopoeial tests in Kanazawa University. A major issue in authenticity investigation was the poor response rate from manufacturers. We could not get any responses from 57 manufacturers, although 86 samples were confirmed to be genuine by 21 manufacturers.

Among all the samples collected, 38, 52 and 48 samples failed in dissolution, content uniformity and/or quality tests at Kanazawa University. Most of the esomeprazole samples failed in all tests (Table 3.4). In the case of amlodipine, which is used to treat

hypertension and chest pain in adults or children, and we found that 6 samples failed the content uniformity test. It is noteworthy that 14 (42.1%) out of 38 samples of domestically produced rabeprazole were of poor quality. Thus, the manufacturers (Cambodian) which are produced poor quality medicines should avoid and imported good quality medicines from the manufacturers.

Finally, it should be noted that our survey had a number of limitations. In particular, budgetary restrictions limited the number of samples that could be collected and the number of outlets that could be sampled. We did not visit all of the same sites in each of the 3 years. Nevertheless, our survey clearly shows that substandard and counterfeit medicines are widely available in Cambodia.

3.6 Conclusion

Poor-quality medicines were still prevalent in Cambodia during 2011-2013. It is desirable to conduct further surveys to continue monitoring the situation. Measures are also needed to improve the quality of domestically manufactured products.

Chapter four

Comparative study between Myanmar and Cambodia

Comparative study between two-countries

◆ According to pharmacopoeial analysis, from the investigation samples in Myanmar we found that 79.7%, 84.7%, 82%, 100%, 100%, 98.7%, and 94.8% samples were passed in assay, content uniformity, dissolution, endotoxin, sterility, identification and microbial assay test respectively (Table 1.5). In the case of antimicrobial samples from Cambodia we found that 90.6%, 86%, 80.4%, 100%, 100%, 100%, 100% samples were passed in assay, content uniformity, dissolution, endotoxin, sterility, identification and microbial assay test respectively (Table 2.8). While in the case in Cambodian lifesaving medicines we found that 86%, 84.8% and 88.9% samples were passed in assay, content uniformity and dissolution test respectively (Table3.4). In Myanmar three GM samples which were failed in both identification and microbial assay test which were counterfeited. Myanmar government confirmed it and announced.

◆ In our one-year investigation, we found counterfeit GM medicines which were sold in Yangon a commercial city in Myanmar. While in Cambodia we conducted above these surveys which included Phnom Penh the capital of Cambodia with five different provinces. In Cambodia we found only poor quality medicines but counterfeit medicines were not detected. It is our hypothesis regarding these surveys, since 1999 there were no systematic survey occurred in Myanmar. Manufacturers took this opportunity and to supply of these type of medicines in Myanmar. In the case in Cambodia regular survey monitoring was in there. We have been reporting each year to the Cambodian authority. Robust action from the Cambodian authority and comparatively better quality of medicines were found in Cambodian markets.

◆ Statistically we found that the average price of failed samples was significantly cheaper than that of passed samples in both of these countries. Manufacturers who did follow GMP might sell these products cheaper than those produced in comply with GMP.

◆ Previously we stablished the evidences about the relationship between the quality of medicines and environmental conditions like as temperature and humidity. These conditions directly enhanced to decrease the quality of medicines. In our investigations, air-conditioning system of drug outlets in both countries were not satisfactory. Above evidences to obtain good quality medicines, it is highly necessary to improve air-conditioning in any type of drug outlet.

◆ We found some samples which were not registered in DDF, Cambodia and Myanmar FDA. But in the case of unregistered samples (all most) from Myanmar were counterfeited which were showing spelling errors on the package of the box. Unregister samples should not be allowed for use in future.

◆ We had collected GM injection from both countries. In Cambodia we found all GM were ampoules. But in the case of Myanmar samples which were collected and some were ampoules and some were vials. We found counterfeit three gentamicin sample which were in ampoule. But, about the vial samples we observed that the samples colour were changed white to yellow before the expiration date. We also observed that the volume of samples were not equal (vial sample). In our laboratory investigation, we realized the samples which containing in to the vials were not properly shield. In this type of medicines should not be used to the patients.

◆ Investigations to Myanmar, we were collected samples from government hospital, privet hospital, community pharmacies, clinical pharmacies and wholesalers. We found counterfeit samples which were keep into only community pharmacies outlets. In this type of drug outlets must be needed special monitoring.

Conclusion of these surveys:

Our surveys were occurred in two low income countries. We found lot of foreign medicines from different manufacturers and countries. In these surveys we found lot of problems such as spelling error on the box, low volume, different package colour, insert messing in a sample box, insert information and package information not matching, loose samples, colour changed before the expiration, not registered samples and non-licenced samples were observed during the observation of samples. In authenticity investigation, from few manufacturers and MRAs replied to us. From both countries, we found huge amounts of poor quality or substandard medicines of samples those were produced in both foreign and domestically. It is our assumption that counterfeit medicine was not found in Cambodia because we have been investigating continuously in this country. But in the case of Myanmar we found counterfeit gentamicin (foreign manufacturers) from their markets and there was no survey occurred in Myanmar from the long time. We observed fail samples were cheaper in both countries than the pass samples.

People not only in this two countries but also all developing countries can get good quality medicines in the future as well as remove counterfeit or poor quality medicines from their markets could be the following ways. If it will occur continuously monitoring (surveys for the evaluation of medicines) or manufacturers which are

producing cheaper medicines cordially must follow actual guideline as well as drug outlets are needed to maintain air-conditioning.

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Annex 1.1 Map of Myanmar

Annex 1.2 Sampling form

Sampling Form

Serial No. ☐ — ☐☐☐ ☐ / /2014

Combating Counterfeit Medicine in Myanmar: 2014

Code : /MY14/

PRODUCT INFORMATION

Contents	Answer	Unknown	Information Source	
			Label	Verbal
Trade name of the product				
Name of active ingredients				
Strength per unit dose	g / mg as			
Salt form				
Dose form of products	☐ Tablets ☐ Ampules ☐ Others :_____			
The product is	☐ Domestically produced ☐ Imported			
Sample Classification	☐ ① Selected companies ☐ ② Unsealed Bottle ☐ ③ PTP/SP without original sealed package ☐ ④ Sealed Bottle ☐ ⑤ PTP/SP with original sealed package			
For ③, the reason why you judge the medicine is not intant	☐ Without original outer package ☐ Different batch number ☐ Changed package in the drug store ☐ Partially sold medicine ☐ Others:_____			
Manufacture	Name			
	Address			
Wholesaler	Name			
	Address			
Batch/Lot number				
Manufactury date	DD / MM / YY			
Expiry date	DD / MM / YY			
Registration number	☐ Yes ⇒ _____ ☐ No			
Package insert	☐ Yes ⇒ ☐ Khmer ☐ English ☐ French ☐ Others: ☐ No			
Price per Unit				
Quantity collected				

OUTLET INFORMATION

Contents	Answer	
Category of the outlet	☐ Pharmacy ☐ Depot A ☐ Depot B ☐ Wholesaler ☐ Illegal _____. ☐ Others_____.	
No. of Pharmacist		
No. of Pharmacy Assistant		
No. of other staff		
Name of the outlet		
Does the shop have air conditioner ?	☐ Yes ☐ No	
Are there any loose medicines?	☐ Yes ☐ No	
For Loose medicine, the container is	☐ the original one supplied during the procurement ☐ changed later on in the drug store	☐ Unknown Information Source ☐ Label ☐ Verbal
How many units of this medicine does the outlet sell ?	_____ units per _____ (e.g. month, year)	

Outlet address	Any comments ? (e.g. Is the medicine kept in a refrigerator ?)	Signature

Annex 1.3 Tool for Visual Inspection of Medicines

	Yes	No	Other Observations
1. PACKAGING			
1.1 Container and Closure			
Does the container and closure protect the product from the outside environment; e.g. is the container properly sealed?			
Do they assure that the product will meet the proper specifications throughout its shelf life?			
Are the container and the closure appropriate for the product inside?			
Is the container safely sealed?			
1.2 Label			
If there is a carton protecting the container, does the label on the carton match the label on the container?			
Is all information on the label legible and indelble?			
1.2.1 The trade (brand) name			
Is the trade name spelled correctly?			
Is the medicinal product (trade name) registered in the country by the Drug Regulatory Authority) ? Is the product legally sold in the coutry?			
Does the symbol ® follow the trade name?			
For blister or foil strip packed products, is the trade name indelibly impressed or imprinted onto the strip?			
1.2.2 The Active ingredient name (scientific name/generic name)			
Is the active ingredient name spelt correctly?			
Do the trade name and the active ingredient names correspond to the registered product?			
1.2.3 The manufacturer's name and logo			
Are the manufacturer's name and logo legible and correct?			
Does the logo or hologram (if applicable) look authentic?			
Does the logo or hologram (if applicable) change colour when viewed from different angles?			

1.2.4 The manufacturer's full address			
Is the manufacturer's full address legible and correct?			
Has this company or its agent registered the product in the country?			
1.2.5 The medicine strength (mg/unit)			
Is the strength - the amount of active ingredient per unit - clearly stated on the label?			
For blister or foil strip packed products, is the medicine strength indelibly impressed or imprinted onto the strip?			
1.2.6 The dosage form (e.g., tablet/capsule)			
Is the dosage form clearly indicated on the container label?			
Does the dosage form stated on the label match the actual dosage form of the medication?			
Is the indicated madicine under this dosage form registered and authorised for sale in the country?			
1.2.7 The number of units per container			
Does the number of dosage units listed on the label match the number of dosage units staated on the container?			
1.2.8 Dosage statement (if appropriate)			
Is the dosage clearly indicated on the label?			
Is the dosage stated on the label appropriate for the madicine in this form and strength?			
Is the product registered and authorised for sale in the country with this dosage?			
1.2.9 The batch (or lot) number			
Does the numbering system on the package correspond to that of the producting company?			
For blister or foil strip packed medicines, is the batch number indelibly impressed or imprinted onto the strip?			
1.2.10 The date of manufacture and the expiry date			
Are the manufacture and expiry dates clearly indicated on the label?			
For blister or foil strip packed products, is the expiry date indelibly impressed or imprinted onto the strip?			

1.2.11 Storage information			
Are the storage conditions indicated on the label?			
Has the product been properly stored?			
1.3 Leaflet or package insert			
Is the package insert printed on the same coloured or same quality paper as the original (If available to compare) or does it look familiar?			
Is the ink on the package insert or packaging smudge-proof?			
Does the informationb on the package insert match the information on the product container?			
2. PHYSICAL CHARACTERISTICS OF TABLETS/CAPSULES			
2.1 Uniformity of Shape			
Are the tablets/capsules uniform in shape?			
2.2 Uniformity of Size			
Are the tablets/capsules uniform in size?			
2.3 Uniformity of Colour			
Are the tablets/capsules uniform in colour?			
2.4 Uniformity of Texture			
Do the tablats have a uniform coating?			
Is the base of the tablets fully covered?			
Are the tablets unifomly polished, free of powder, and non-sticking?			
2.5 Markings (scoring, letters, etc)			
Are markings uniform and identical?			
Does the logo (if present) match that of the manufacturing company?			
2.6 Breaks, Cracks and Splits			
Are the tablets/capsules free of breaks, cracks, splits or pinholes?			
2.7 Embedded surface spots or contamination			
Are the tablets/capsules free of embedded surface spots and foreign particle contamination?			
2.8 Presence of empty capsules in the case of asample of capsules			
Is the sample examined free of empty capsules?			
2.9 Smell			
Does the medicine smell the same as the original (If available)? Does it smell peculiar?			

Annex 1.4 Authenticity form for manufactures

KANAZAWA University
Institute of Medical, Pharmaceutical and Health Sciences

QUESTIONNAIRE FOR AUTHENTICITY INVESTIGATION

MANUFACTURER:

Scope: The purpose of this questionnaire is to authenticate a medicinal sample/s collected in conjunction with the anti-counterfeit initiatives of the Ministry Health, Myanmar

Instructions:

- Please refer to the attached sample(s) or photos and check appropriate boxes ☑ for your answer.
- Please provide detailed information whenever it is required.

REGISTRATION			
1	Do you have a License Number in the manufacturing country issued by the Medicine Regulatory Authority? ☐Yes/ Detailed number; _____ ☐No		
2	Are you certified on Good Manufacturing Practices?	☐Yes	☐No
3	If certified, please detail the name of certifying authority.		
PACKAGING AND MARKETING			
4	Are these packages/containers of the samples made by your company originally?	☐Yes	☐No
5	If you checked 'No' for the above question, please let us know who prepare the package: ☐distributor ☐other company;_____ ☐unknown		
6	During shipment to importing country/Myanmar, do you transport your medicines separately from their packages/containers?	☐Yes	☐No

CONTACT INFORMATION	
Responded by-	Date: / /
Name:	
Professional affiliation/position:	
Company full address:	
Tel / Fax:	E-mail:

Annex 1.5 authenticity form for sample

KANAZAWA University
Institute of Medical, Pharmaceutical and Health Sciences

SAMPLE CODE:

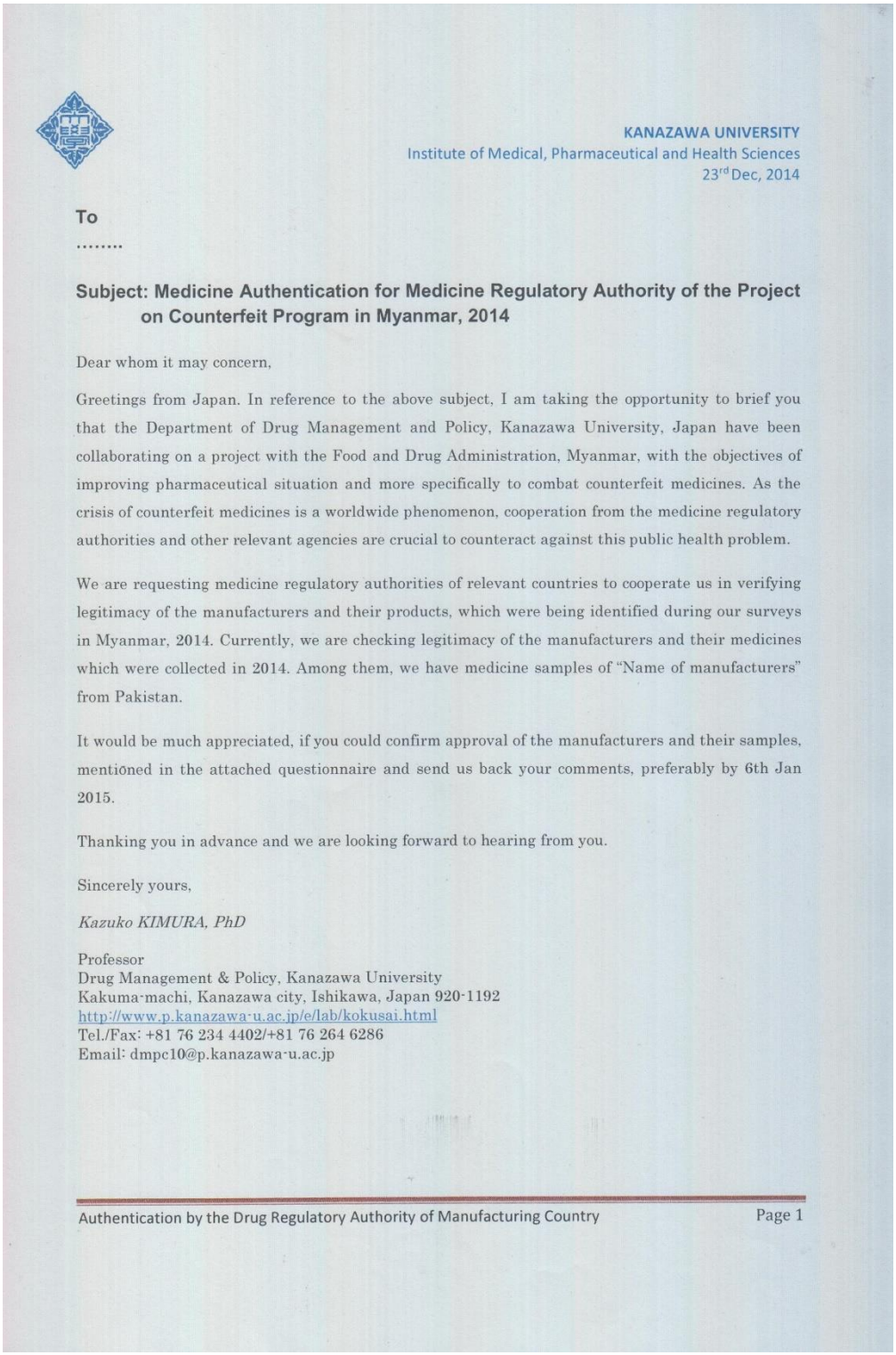
SAMPLE AUTHENTICATION				
	Sample's description		Pl. check appropriate box, if the information provided is identical to your genuine sample	
1	Trade Name		☐Yes	☐No
2	Active Ingredient & Strength		☐Yes	☐No
3	Dosage Form		☐Yes	☐No
4	Manufacturer's Name		☐Yes	☐No
5	Manufacturer's Address		☐Yes	☐No
6	Batch/Lot Number:		☐Yes	☐No
7	Manufacturing Date:		☐Yes	☐No
8	Expiry Date:		☐Yes	☐No
9	Distributor's Name		☐Yes	☐No
10	Distributor's Country		☐Yes	☐No
11	Myanmar Registration No.		☐Yes	☐No
12	Manufacturing License Number		☐Yes	☐No
13	Is the logo authentic?		☐Yes	☐No
14	Is the trade name written appropriately (font, spell, ®)?	font	☐Yes	☐No
		spell	☐Yes	☐No
		®	☐Yes	☐No
15	Are the active ingredient(s) name(s) written appropriately?		☐Yes	☐No
16	Does the physical characteristics of the dosage form are uniform and consistent?	form	☐Yes	☐No
		shape	☐Yes	☐No
		color	☐Yes	☐No
		coating	☐Yes	☐No
		size	☐Yes	☐No
17	Is the product under this dosage form registered and authorized for sale in Myanmar?		☐Yes	☐No
18	Please write correct information in the space provided below, if you checked 'No' to any of the above points (1-17)			
19	Is this medicine Genuine or Counterfeit?		**☐Genuine**	**☐Counterfeit**

20	If you checked 'Counterfeit' for the above question, please indicate the details about the difference of Genuine product and the Counterfeit one.

MARKETING IN SAMPLING COUNTRY	
21	Is the sample medicine approved by the Drug Regulatory Authority in the manufacturing country? ☐Yes / Provide approval / registration number: _____ ☐No
22	Is the sample medicine approved for marketing in Myanmar? ☐Yes ☐No
23	If you checked 'No' to the above question, please answer following two additional questions: i. Please write the countries where this medicine is approved for marketing. ii. Do you know that this medicine is sold in Myanmar? ☐Yes ☐No

Pictures of Sample:

Annex 1.6 authenticity e-mail to MRAs



KANAZAWA UNIVERSITY
Institute of Medical, Pharmaceutical and Health Sciences
23rd Dec, 2014

To
.....

Subject: Medicine Authentication for Medicine Regulatory Authority of the Project on Counterfeit Program in Myanmar, 2014

Dear whom it may concern,

Greetings from Japan. In reference to the above subject, I am taking the opportunity to brief you that the Department of Drug Management and Policy, Kanazawa University, Japan have been collaborating on a project with the Food and Drug Administration, Myanmar, with the objectives of improving pharmaceutical situation and more specifically to combat counterfeit medicines. As the crisis of counterfeit medicines is a worldwide phenomenon, cooperation from the medicine regulatory authorities and other relevant agencies are crucial to counteract against this public health problem.

We are requesting medicine regulatory authorities of relevant countries to cooperate us in verifying legitimacy of the manufacturers and their products, which were being identified during our surveys in Myanmar, 2014. Currently, we are checking legitimacy of the manufacturers and their medicines which were collected in 2014. Among them, we have medicine samples of "Name of manufacturers" from Pakistan.

It would be much appreciated, if you could confirm approval of the manufacturers and their samples, mentioned in the attached questionnaire and send us back your comments, preferably by 6th Jan 2015.

Thanking you in advance and we are looking forward to hearing from you.

Sincerely yours,

Kazuko KIMURA, PhD

Professor
Drug Management & Policy, Kanazawa University
Kakuma-machi, Kanazawa city, Ishikawa, Japan 920-1192
http://www.p.kanazawa-u.ac.jp/e/lab/kokusai.html
Tel./Fax: +81 76 234 4402/+81 76 264 6286
Email: dmpc10@p.kanazawa-u.ac.jp

KANAZAWA UNIVERSITY
Institute of Medical, Pharmaceutical and Health Sciences
23rd Dec, 2014

MEDICINE AUTHENTICATION FORM
For Drug Regulatory Authority of Manufacturing Country

Please provide necessary information for each of the manufacturers and their medicine products mentioned below. If you have additional information that might be important to judge whether the medicine is counterfeit or not, please indicate such in the remarks column.

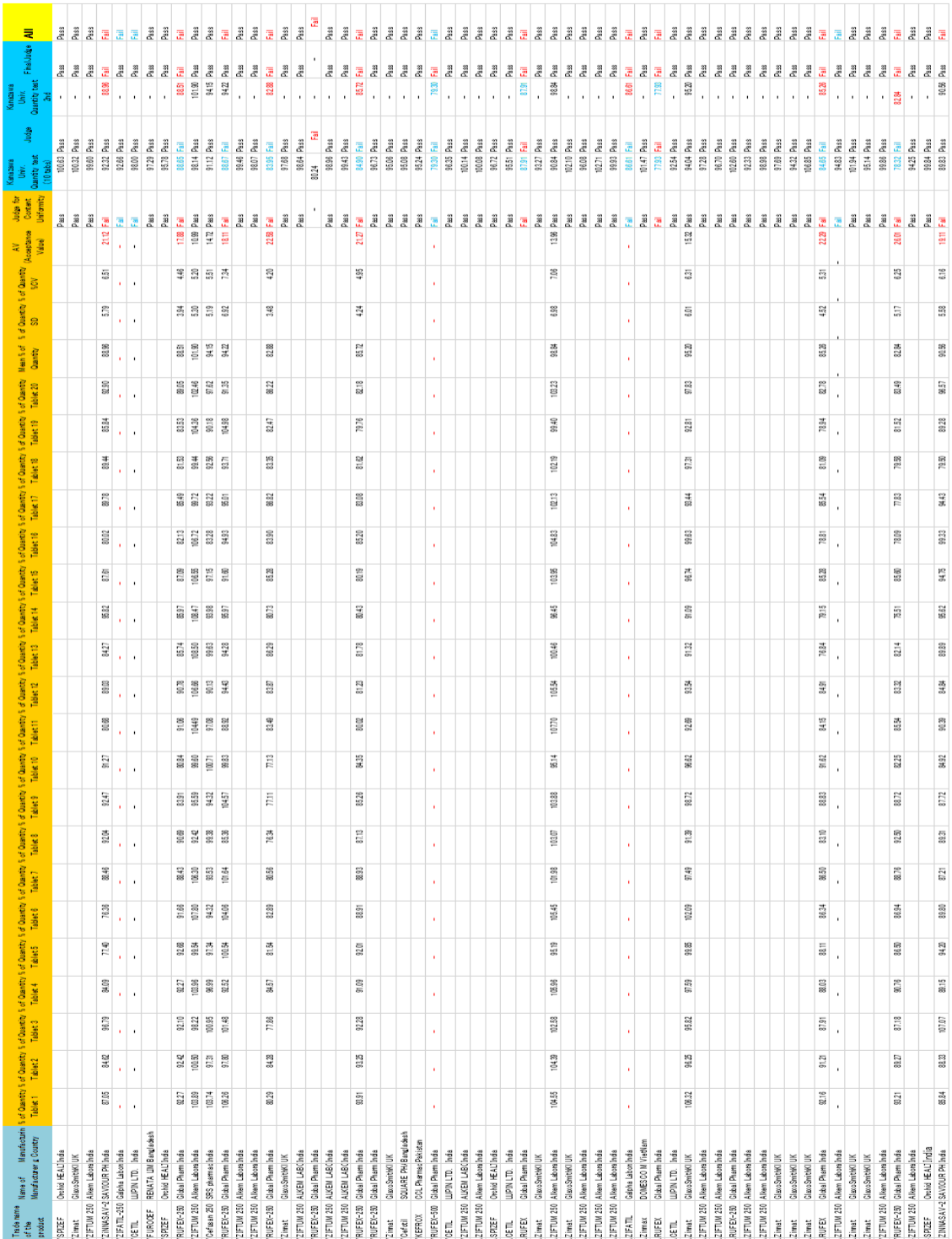
Name of the Manufacturer: **Country:**			
1. Is this manufacturer licensed by the Drug Regulatory Authority of your country? □Yes □No 2. If Yes, please mention manufacturer's License Number:			
3. Is this a GMP qualified manufacturer of your country? □Yes □No			
Products			
Please check an appropriate box, if the regulatory authority of your country approves the manufacturer to produce mentioned medicine(s).			
Trade Name, strength, form	Active ingredient	Approval status	Remarks (if any)
		□Yes □No	
		□Yes □No	

Thank you very much for your kind cooperation

Annex 1.7 Result of quantity test and content uniformity test (1st stage) [CXM]

Serial No.	Sample Code	Trade name of the product	Name of Manufacturer & Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	% of Quantity Tablet 7	% of Quantity Tablet 8	% of Quantity Tablet 9	% of Quantity Tablet 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge
A-005	A005/MM14/ SPIZEF	Orchid HEAL India	Orchid HEAL India	104.92	104.54	100.00	102.70	95.88	99.40	94.86	106.87	101.22	98.94	100.6	3.9	3.9	9.372893126	Pass
A-006	A006/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	104.21	103.39	98.63	97.51	93.65	103.10	106.08	98.50	95.83	102.27	100.3	4.1	4.0	9.731768808	Pass
A-007	A007/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	102.27	103.86	100.48	102.58	98.18	97.12	100.36	100.98	97.48	92.73	99.6	3.3	3.3	7.89	Pass
A-016	A016/MM14/ ZINNASAV-2	SAVIOUR PH India	Galpha Labori India	92.41	93.57	91.85	95.51	95.75	90.01	89.77	84.34	88.41	101.55	92.3	4.7	5.1	17.48	Fail
A-017	A017/MM14/ ZIFATIL-250	Galpha Labori India	Galpha Labori India	84.42	99.25	100.84	85.26	90.85	90.97	97.08	91.92	93.14	92.91	92.7	5.4	5.8	18.72	Fail
A-018	A018/MM14/ CETIL	LUPIN LTD. India	LUPIN LTD. India	85.61	97.53	104.85	104.61	90.77	107.86	98.31	94.87	97.54	98.02	98.0	6.7	6.8	16.58	Fail
A-019	A019/MM14/ FUROQEF	RENATA LIM Bangladesh	RENATA LIM Bangladesh	99.58	97.87	93.20	95.87	93.71	103.43	100.62	96.39	98.09	95.14	97.3	3.2	3.3	9.00	Pass
A-025	A025/MM14/ SPIZEF	Orchid HEAL India	Orchid HEAL India	94.08	101.01	89.89	94.86	93.99	95.64	99.03	101.53	94.92	92.86	95.8	3.7	3.8	11.55	Pass
A-030	A030/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	92.98	91.66	89.14	90.87	92.74	88.74	88.45	86.30	82.74	82.84	88.6	3.7	4.2	18.76	Fail
A-036	A036/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	104.08	102.32	92.47	95.41	111.73	93.88	93.39	101.14	92.26	94.69	98.1	6.4	6.6	15.45	Fail
A-037	A037/MM14/ Cefixan 250	SRS pharmac India	SRS pharmac India	91.27	93.27	96.13	88.28	98.09	91.63	91.59	94.10	87.74	79.11	91.1	5.3	5.8	20.06	Fail
A-048	A048/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	95.65	100.96	82.79	86.92	84.50	92.64	87.53	87.83	84.09	83.79	88.7	5.9	6.7	24.08	Fail
A-052	A052/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	92.28	99.85	94.71	96.54	95.82	98.57	99.74	103.67	107.73	105.66	99.5	5.0	5.0	11.90	Pass
A-054	A054/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	101.48	100.22	91.88	103.28	95.38	105.52	97.11	98.08	92.65	95.07	98.1	4.5	4.6	11.28	Pass
A-057	A057/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	87.87	87.87	87.65	82.96	87.90	82.50	85.36	79.08	77.86	80.46	84.0	3.9	4.7	23.95	Fail
A-058	A058/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	95.38	104.18	100.01	98.10	103.39	99.45	93.58	100.25	90.67	91.76	97.7	4.7	4.8	12.04	Pass
A-063	A063/MM14/ ZIFTUM 250	ALKEM LABO India	ALKEM LABO India	99.58	95.59	96.90	102.68	100.60	103.08	94.12	99.93	98.40	95.48	98.6	3.1	3.1	7.38	Pass
A-068	A068/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	85.13	80.97	74.82	—	—	—	—	—	—	—	80.2	—	—	—	—
A-071	A071/MM14/ ZIFTUM 250	ALKEM LABO India	ALKEM LABO India	107.29	97.04	100.25	99.21	101.42	104.80	95.76	99.53	94.60	89.71	99.0	5.1	5.1	12.13	Pass
A-074	A074/MM14/ ZIFTUM 250	ALKEM LABO India	ALKEM LABO India	105.17	99.99	101.85	103.65	98.37	100.92	98.68	93.11	93.86	98.67	99.4	3.8	3.9	9.21	Pass
A-079	A079/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	86.23	86.08	82.00	86.17	84.76	88.14	83.31	89.02	81.19	82.07	84.9	2.7	3.2	20.05	Fail
A-085	A085/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	98.68	88.40	99.10	101.87	98.85	93.01	98.22	95.66	96.45	97.29	96.7	3.7	3.9	10.77	Pass
A-086	A086/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	94.85	92.47	90.91	95.96	99.71	94.09	96.69	97.74	93.76	94.46	95.1	2.6	2.7	9.60	Pass
A-089	A089/MM14/ Cefotil	SQUARE PH/ Bangladesh	SQUARE PH/ Bangladesh	97.95	97.60	93.43	92.10	101.08	87.19	96.73	96.72	93.55	94.45	95.1	3.8	4.0	12.63	Pass
A-095	A095/MM14/ KEFROX	OCL Pharmac Pakistan	OCL Pharmac Pakistan	89.41	99.51	95.97	94.42	103.65	96.10	90.11	97.75	94.44	90.99	95.2	4.4	4.6	13.88	Pass
A-099	A099/MM14/ RUFEX-500	Global Pharm India	Global Pharm India	79.62	80.37	82.34	80.60	76.43	78.62	81.50	79.29	78.70	75.53	79.3	2.1	2.7	24.28	Fail
A-102	A102/MM14/ CETIL	LUPIN LTD. India	LUPIN LTD. India	98.44	99.04	95.46	93.58	98.00	95.74	100.25	97.12	98.56	87.30	96.3	3.7	3.9	11.12	Pass
A-104	A104/MM14/ ZIFTUM 250	ALKEM LABO India	ALKEM LABO India	103.02	98.07	99.18	103.84	101.83	103.11	94.54	97.96	102.81	97.01	100.1	3.2	3.2	7.67	Pass
B-002	B-002/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	96.55	104.47	106.58	100.60	100.41	102.25	90.34	103.61	96.69	99.31	100.1	4.7	4.7	11.27	Pass
B-003	B-003/MM14/ SPIZEF	Orchid HEAL India	Orchid HEAL India	94.9	96.3	96.4	94.2	99.8	100.9	95.0	95.7	91.2	103.1	96.7	3.5	3.6	10.22	Pass
B-004	B-004/MM14/ CETIL	LUPIN LTD. India	LUPIN LTD. India	98.99	100.25	99.81	95.66	94.94	97.36	89.83	90.59	94.11	93.58	95.5	3.6	3.8	11.71	Pass
B-023	B-023/MM14/ RUFEX	Global Pharm India	Global Pharm India	86.47	88.94	86.99	95.59	93.94	92.55	73.24	90.08	89.30	82.01	87.9	6.5	7.4	26.13	Fail
B-027	B-027/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	96.26	93.06	95.03	91.98	95.18	90.38	93.66	86.06	98.76	92.34	93.3	3.5	3.7	13.57	Pass
B-029	B-029/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	98.08	99.17	97.64	88.44	89.52	93.13	83.94	84.61	78.85	95.15	90.8	6.9	7.6	24.34	Fail
B-030	B-030/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	97.84	98.27	109.33	101.97	98.36	104.72	97.52	111.74	108.12	93.15	102.1	6.1	6.0	15.27	Pass
B-031	B-031/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	96.67	101.02	94.08	96.38	93.86	95.06	93.75	96.25	96.24	97.52	96.1	2.2	2.3	7.63	Pass
B-034	B-034/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	101.07	100.73	104.94	106.81	101.49	97.11	102.96	106.33	102.82	102.79	102.7	2.9	2.8	8.11	Pass
B-038	B-038/MM14/ ZIFTUM 250	Alkem Labora India	Galpha Labori India	105.30	92.74	104.55	105.08	97.92	98.05	98.24	100.54	98.83	98.10	99.9	4.0	4.0	9.59	Pass
B-042	B-042/MM14/ ZIFATIL	Galpha Labori India	Galpha Labori India	83.66	84.52	86.32	91.22	84.44	85.86	91.58	84.65	93.10	80.82	86.6	4.0	4.6	21.48	Fail
B-044	B-044/MM14/ Zinnax	DOMESCO M VietNam	DOMESCO M VietNam	102.47	102.35	102.44	104.48	103.97	103.72	102.78	98.97	97.20	96.30	101.5	2.9	2.9	6.98	Pass
B-047	B-047/MM14/ RUFEX	Global Pharm India	Global Pharm India	71.12	69.88	88.62	76.65	74.10	77.86	88.15	85.61	74.36	74.00	77.9	7.0	9.0	37.37	Fail
B-052	B-052/MM14/ CETIL	LUPIN LTD. India	LUPIN LTD. India	91.71	97.36	88.44	93.86	88.52	96.88	92.86	90.31	92.94	92.51	92.5	3.0	3.3	13.24	Pass
B-053	B-053/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	104.46	85.18	85.58	83.73	90.96	104.88	89.09	90.42	102.98	103.08	94.0	8.8	9.3	25.50	Fail
B-063	B-063/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	98.72	91.94	97.51	92.91	97.18	91.92	109.19	92.38	98.29	102.77	97.3	5.5	5.7	14.50	Pass
B-066	B-066/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	97.47	99.41	97.77	99.32	92.59	92.40	94.94	95.56	96.13	101.41	96.7	2.9	3.0	8.88	Pass
B-067	B-067/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	97.63	100.15	107.00	101.46	107.64	106.13	101.37	101.88	100.85	101.86	102.6	3.2	3.2	8.89	Pass
B-076	B-076/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	97.22	96.14	92.13	89.04	90.90	91.00	95.82	93.73	84.56	92.74	92.3	3.8	4.1	15.21	Pass
B-079	B-079/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	101.08	94.44	98.21	99.11	103.97	102.67	97.27	97.77	97.49	97.75	99.0	2.8	2.9	6.80	Pass
B-080	B-080/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	97.64	99.42	97.71	100.36	97.58	96.02	98.42	96.52	96.50	96.74	97.7	1.4	1.4	4.12	Pass
B-086	B-086/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	92.29	98.58	98.56	91.81	102.01	90.37	90.05	93.33	92.23	94.00	94.3	4.0	4.3	13.81	Pass
B-089	B-089/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	109.93	105.57	104.26	115.00	103.68	107.96	107.55	110.73	101.57	102.22	106.8	4.2	4.0	15.48	Pass
B-093	B-093/MM14/ RUFEX	Global Pharm India	Global Pharm India	88.76	91.12	80.84	80.41	75.56	87.75	83.93	82.01	89.50	86.58	84.6	4.9	5.8	25.68	Fail
B-100	B-100/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	93.01	94.13	107.34	91.54	94.24	102.22	93.05	92.89	89.85	90.01	94.8	5.6	5.9	17.08	Fail
B-101	B-101/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	101.68	103.63	103.61	99.44	102.50	115.40	101.56	97.35	95.65	98.59	101.9	5.4	5.3	13.47	Pass
B-102	B-102/MM14/ Zinnat	GlaxoSmithKli UK	GlaxoSmithKli UK	94.09	96.03	98.31	97.15	93.26	92.67	95.69	99.97	95.30	96.11	95.9	2.2	2.3	8.01	Pass
B-104	B104/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	99.74	105.46	105.23	100.22	101.84	95.14	97.11	101.63	90.14	102.08	99.9	4.7	4.7	11.22	Pass
B-111	B111/MM14/ RUFEX-250	Global Pharm India	Global Pharm India	77.76	80.96	83.08	77.55	76.53	76.92	78.97	79.20	74.70	77.48	78.3	2.4	3.0	25.88	Fail
PA-001	PA001/MM14/ ZIFTUM 250	Alkem Labora India	Alkem Labora India	93.01	94.13	101.56	91.54	94.24	102.22	93.05	92.89	89.85	90.01	94.3	4.3	4.6	14.57	Pass
PA-002	PA002/MM14/ SPIZEF	Orchid HEAL India	Orchid HEAL India	103.65	100.90	102.00	99.25	97.83	96.97	102.27	102.52	93.13	99.91	99.8	3.2	3.2	7.64	Pass
PB-001	PB-001/MM1 ZINNASAV-2	SAVIOUR PH India	SAVIOUR PH India	88.20	90.25	93.58	92.14	90.62	79.25	94.40	95.94	85.54	88.40	89.83	4.87	5.42	20.36	Fail

Content uniformity test for second stage (CXM):



Serial No	Sample Code of the product	Trade name	Name of Manufacturer	Manufacturing Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	% of Quantity Tablet 7	% of Quantity Tablet 8	% of Quantity Tablet 9	% of Quantity Tablet 10	% of Quantity Tablet 11	% of Quantity Tablet 12	% of Quantity Tablet 13	% of Quantity Tablet 14	% of Quantity Tablet 15	% of Quantity Tablet 16	% of Quantity Tablet 17	% of Quantity Tablet 18	% of Quantity Tablet 19	% of Quantity Tablet 20	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV Acceptance Value	Judge for Content Uniformity	Kevaluwa Univ Quantity test (10 Tab)	Judge	Kevaluwa Univ Quantity test Jar	Final Judge	All
A-005	A005 /MAY14/SPIZEF	Orchid HEALthIndia																											Pass	100.83	Pass	-	Pass	Pass
A-006	A006 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	100.32	Pass	-	Pass	Pass
A-007	A007 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	99.60	Pass	-	Pass	Pass
A-008	A008 /MAY14/ZINNASAV-2.5AVIDUR Philindia				87.65	84.82	98.79	84.09	77.46	79.38	88.46	82.94	82.47	84.27	89.68	89.03	84.27	85.82	87.01	89.02	88.78	89.44	85.84	92.90	87.03	5.79	6.61	21.10	Fail	83.32	Pass	89.98	Fail	Fail
A-017	A017 /MAY14/ZIFALTIL-200	Galpha Laboratories India			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	82.66	Pass	-	Pass	Fail
A-018	A018 /MAY14/OETIL	LUPIN LTD. India			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	88.00	Pass	-	Pass	Fail
A-019	A019 /MAY14/FUROSOEF	RENATA LIMI Bangladesh																											Pass	97.20	Pass	-	Pass	Pass
A-025	A025 /MAY14/SPIZEF	Orchid HEALthIndia																											Pass	95.70	Pass	-	Pass	Pass
A-000	A000 /MAY14/RUFEX-20	Glaxo Pharm.India			92.27	92.42	92.10	92.27	92.08	88.43	91.66	86.49	83.91	88.64	91.06	90.78	85.74	85.97	87.09	82.13	85.49	81.53	83.53	89.05	88.91	3.94	4.46	113.88	Fail	88.65	Fail	88.91	Fail	Fail
A-006	A006 /MAY14/ZIFTUM 200	Ahlem Laboratories			103.89	100.50	89.22	103.96	91.54	107.80	106.20	82.42	85.59	89.60	104.49	109.86	103.50	108.47	104.55	99.72	89.72	89.44	104.36	102.46	101.90	5.30	5.20	110.99	Pass	88.14	Pass	101.90	Pass	Pass
A-007	A007 /MAY14/Cefexan 250	SRS pharmaceuticals India			103.74	97.31	100.95	96.89	91.74	94.32	89.53	89.38	94.32	100.71	97.08	90.13	99.63	93.98	97.15	83.28	93.22	92.59	90.18	97.62	94.15	5.19	5.51	114.72	Pass	91.12	Pass	94.15	Pass	Pass
A-048	A048 /MAY14/RUFEX-20	Glaxo Pharm.India			109.28	97.99	101.48	98.52	100.54	104.96	109.88	85.38	94.57	99.83	99.82	94.43	94.33	96.97	91.66	94.83	96.01	93.71	104.98	91.35	94.22	6.02	7.34	118.11	Fail	89.67	Fail	94.22	Pass	Fail
A-052	A052 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	99.46	Pass	-	Pass	Pass
A-054	A054 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	98.07	Pass	-	Pass	Pass
A-057	A057 /MAY14/RUFEX-20	Glaxo Pharm.India			80.29	84.28	77.86	84.57	81.54	82.89	86.56	76.94	77.11	77.13	83.49	83.87	86.29	80.23	85.88	83.90	88.62	83.35	82.41	86.22	82.88	3.49	4.20	123.88	Fail	83.95	Fail	82.88	Fail	Fail
A-058	A058 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	97.88	Pass	-	Pass	Pass
A-063	A063 /MAY14/ZIFTUM 200	ALKEM LABS India																											Pass	98.64	Pass	-	Pass	Pass
A-068	A068 /MAY14/RUFEX-20	Glaxo Pharm.India																										-	80.24	Fail	-	-	-	Fail
A-071	A071 /MAY14/ZIFTUM 200	ALKEM LABS India																											Pass	98.98	Pass	-	Pass	Pass
A-074	A074 /MAY14/ZIFTUM 200	ALKEM LABS India																											Pass	99.43	Pass	-	Pass	Pass
A-079	A079 /MAY14/RUFEX-20	Glaxo Pharm.India			80.91	83.25	82.28	91.09	92.01	88.91	88.93	87.13	83.28	84.35	81.23	81.70	80.43	86.19	85.20	82.08	81.62	78.70	82.18	88.72	84.90	4.95	5.81	121.07	Fail	85.72	Fail	84.90	Fail	Fail
A-085	A085 /MAY14/RUFEX-20	Glaxo Pharm.India																											Pass	98.73	Pass	-	Pass	Pass
A-088	A088 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	95.68	Pass	-	Pass	Pass
A-089	A089 /MAY14/Cefadil	SQUARE Pharmaceuticals Bangladesh																											Pass	95.08	Pass	-	Pass	Pass
A-095	A095 /MAY14/KEPROX	OCL Pharmaceuticals Pakistan																											Pass	95.24	Pass	-	Pass	Pass
A-099	A099 /MAY14/RUFEX-500	Glaxo Pharm.India			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	79.30	Fail	-	Fail	Fail
A-102	A102 /MAY14/OETIL	LUPIN LTD. India																											Pass	98.38	Pass	-	Pass	Pass
A-104	A104 /MAY14/ZIFTUM 200	ALKEM LABS India																											Pass	100.14	Pass	-	Pass	Pass
B-002	B-002 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	100.08	Pass	-	Pass	Pass
B-003	B-003 /MAY14/SPIZEF	Orchid HEALthIndia																											Pass	98.72	Pass	-	Pass	Pass
B-004	B-004 /MAY14/OETIL	LUPIN LTD. India																											Pass	95.51	Pass	-	Pass	Pass
B-023	B-023 /MAY14/RUFEX	Glaxo Pharm.India																											Fail	87.91	Fail	87.91	Fail	Fail
B-027	B-027 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	93.27	Pass	-	Pass	Pass
B-029	B-029 /MAY14/ZIFTUM 200	Ahlem Laboratories			104.55	104.39	102.58	105.66	96.19	105.45	109.88	103.07	103.88	95.14	107.79	105.54	100.46	98.45	103.95	104.83	102.13	102.19	99.40	103.23	98.94	6.88	7.06	113.96	Pass	98.84	Pass	98.94	Pass	Pass
B-030	B-030 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	100.10	Pass	-	Pass	Pass
B-031	B-031 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	99.08	Pass	-	Pass	Pass
B-034	B-034 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	100.21	Pass	-	Pass	Pass
B-038	B-038 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	99.93	Pass	-	Pass	Pass
B-042	B-042 /MAY14/ZIFALTIL	Galpha Laboratories India			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	89.61	Fail	89.61	Fail	Fail
B-044	B-044 /MAY14/Zimax	DOMESCO M Vietnam																											Pass	101.47	Pass	-	Pass	Pass
B-047	B-047 /MAY14/RUFEX	Glaxo Pharm.India																											Fail	77.93	Fail	77.93	Fail	Fail
B-052	B-052 /MAY14/OETIL	LUPIN LTD. India																											Pass	92.54	Pass	-	Pass	Pass
B-053	B-053 /MAY14/Zimet	GlaxoSmithKl UK	109.32	94.25	89.82	97.59	99.85	102.09	97.49	91.39	99.72	96.62	93.09	93.54	91.32	91.09	96.74	99.63	92.44	97.21	92.81	97.83	94.20	6.01	6.31	115.30	Pass	94.04	Pass	95.20	Pass	Pass
B-063	B-063 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	97.28	Pass	-	Pass	Pass
B-066	B-066 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	96.70	Pass	-	Pass	Pass
B-067	B-067 /MAY14/RUFEX-20	Glaxo Pharm.India																											Pass	102.60	Pass	-	Pass	Pass
B-076	B-076 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	92.33	Pass	-	Pass	Pass
B-079	B-079 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	98.88	Pass	-	Pass	Pass
B-060	B-060 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	97.69	Pass	-	Pass	Pass
B-086	B-086 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	94.32	Pass	-	Pass	Pass
B-089	B-089 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	100.85	Pass	-	Pass	Pass
B-093	B-093 /MAY14/RUFEX	Glaxo Pharm.India	82.16	91.21	87.91	88.03	83.11	80.34	88.50	83.10	88.83	91.42	84.15	84.80	78.84	78.15	85.28	78.81	85.54	81.09	78.94	82.78	85.28	4.52	5.31	122.28	Fail	84.65	Fail	85.28	Fail	Fail
B-100	B-100 /MAY14/ZIFTUM 200	Ahlem Laboratories	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	84.63	Pass	-	Pass	Fail
B-101	B-101 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	101.94	Pass	-	Pass	Pass
B-102	B-102 /MAY14/Zimet	GlaxoSmithKl UK																											Pass	95.14	Pass	-	Pass	Pass
B-104	B104 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	99.88	Pass	-	Pass	Pass
B-111	B111 /MAY14/RUFEX-20	Glaxo Pharm.India	80.21	89.27	87.10	90.70	84.50	89.94	88.70	82.50	88.72	82.35	85.54	83.32	82.14	79.51	85.60	79.09	77.93	79.58	81.52	83.49	82.94	5.17	6.25	120.91	Fail	79.32	Fail	82.94	Fail	Fail
PA-001	PA001 /MAY14/ZIFTUM 200	Ahlem Laboratories																											Pass	94.25	Pass	-	Pass	Pass
PA-002	PA002 /MAY14/SPIZEF	Orchid HEALthIndia																											Pass	99.84	Pass	-	Pass	Pass
PB-001	PB-001 /MAY14/ZINNASAV-2.5AVIDUR Philindia		86.84	88.33	101.07	89.15	94.20	89.80	87.21	88.31	87.72	84.92	84.92	84.94	89.89	89.62	94.78	99.33	94.43	78.90	89.28	96.57	90.58	6.58	6.18	109.11	Fail	89.83	Pass	90.58	Pass	Fail

Dissolution test 6 tablets for first stage (CXM):

Cefuroxime tablets Myanmar project 2014

Kanazawa Univ. Dissolution test (USP 1st stage) Q=60% 15分

ID	Serial No.	Sample Code	Trade name of the product	Name of Manufacturer	Manufacturing Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge at 15分
3	A-005	A005/MM14/YG/01/HG/CX	SPIZEF	Orchid HEALTHCAR	India	101.01	96.57	95.96	96.92	99.78	95.69	97.65	2.2	2.26	Pass
4	A-006	A006/MM14/YG/01/HG/CX	Zinnat	GlaxoSmithKline	UK	77.86	86.26	87.94	87.54	91.17	91.77	87.09	5.01	5.75	Pass
5	A-007	A007/MM14/YG/01/HG/CX	ZIFTUM 250	Alkem Laboratories L	India	94.80	96.21	95.20	98.97	95.40	97.02	96.27	1.54	1.60	Pass
6	A-016	A016/MM14/YG/01/HG/CX	ZINNASAV-250	SAVIOUR PHARMAC	India	86.13	86.73	80.62	77.52	85.79	82.70	83.25	3.66	4.39	Pass
7	A-017	A017/MM14/YG/01/HG/CX	ZIFATIL-250	Galpha Laboratories	India	108.91	95.81	110.33	106.09	107.70	113.48	107.05	6.06	5.66	Pass
8	A-018	A018/MM14/YG/01/HG/CX	OETIL	LUPIN LTD.	India	100.74	93.64	93.71	101.42	102.10	97.87	98.25	3.82	3.89	Pass
9	A-019	A019/MM14/YG/01/HG/CX	FUROCEF	RENATA LIMITED	Bangladesh	69.59	77.86	74.23	86.87	83.51	82.50	79.09	6.43	8.13	Pass
10	A-025	A025/MM14/YG/04/C/CXM	SPIZEF	Orchid HEALTHCAR	India	84.11	96.75	94.19	78.87	95.81	91.57	90.22	7.18	7.96	Pass
11	A-030	A030/MM14/YG/02/C/CXM	RUFEX-250	Global Pharma Healt	India	80.68	87.20	71.81	60.60	86.93	77.86	77.52	10.11	13.05	Fail
12	A-036	A036/MM14/YG/01/Ocl /C	ZIFTUM 250	Alkem Laboratories L	India	100.40	94.87	87.70	95.28	92.61	92.96	93.97	4.15	4.41	Pass
13	A-037	A037/MM14/YG/01/Ocl/C	Cefusan 250	SRS pharmaceutical	India	94.46	94.66	96.71	95.89	95.55	93.84	95.19	1.05	1.11	Pass
14	A-048	A048/MM14/YG/06/C/CXM	RUFEX-250	Global Pharma Healt	India	66.77	63.95	65.56	66.37	66.57	68.99	66.37	1.65	2.48	Fail
15	A-052	A052/MM14/YG/02/HG/CX	ZIFTUM 250	Alkem Laboratories L	India	96.81	97.35	98.50	97.22	100.85	101.05	98.63	1.88	1.91	Pass
16	A-054	A054/MM14/YG/02/G/CXM	ZIFTUM 250	Alkem Laboratories L	India	96.88	100.24	93.79	97.82	98.63	98.83	97.70	2.22	2.27	Pass
17	A-057	A057/MM14/YG/01/HP/CX	RUFEX-250	Global Pharma Healt	India	51.24	71.52	79.71	71.72	79.92	72.54	71.11	10.48	14.73	Fail
18	A-058	A058/MM14/YG/HP/CXM	Zinnat	GlaxoSmithKline	UK	94.19	91.57	91.17	88.14	96.81	93.39	92.55	2.96	3.20	Pass
19	A-063	A063/MM14/YG/01/Ocl/C	ZIFTUM 250	ALKEM LABORATOI	India	101.01	93.84	91.59	92.00	94.39	95.89	94.79	3.43	3.62	Pass
20	A-068	A068/MM14/YG/02/C/CXM	RUFEX-250	Global Pharma Healt	India	78.46	80.68	70.40	63.34	69.59	71.61	72.35	6.32	8.74	Fail
21	A-071	A071/MM14/YG/01/HG/CX	ZIFTUM 250	ALKEM LABORATOI	India	96.61	96.68	104.14	97.82	92.78	94.40	97.07	3.91	4.03	Pass
22	A-074	A074/MM14/YG/01/C/CXM	ZIFTUM 250	ALKEM LABORATOI	India	90.77	91.98	87.74	91.17	88.88	86.73	89.54	2.08	2.32	Pass
23	A-079	A079/MM14/YG/02/Ocl/C	RUFEX-250	Global Pharma Healt	India	64.69	62.27	63.95	81.09	58.91	62.00	65.48	7.90	12.07	Fail
24	A-085	A085/MM14/YG/02/HP/CX	RUFEX-250	Global Pharma Healt	India	64.35	59.23	66.88	59.03	63.94	70.22	63.94	4.35	6.80	Fail
25	A-086	A086/MM14/YG/02/HP/CX	Zinnat	GlaxoSmithKline	UK	82.97	81.89	85.32	89.62	85.12	87.94	85.48	2.92	3.41	Pass
26	A-089	A089/MM14/YG/01/W/CXM	Cefotil	SQUARE PHARMAC	Bangladesh	BP	—	—	—	—	—	—	—	—	—
27	A-095	A095/MM14/YG/03/W/CXM	KEFROX	OCL Pharmaceutical	Pakistan	BP	—	—	—	—	—	—	—	—	—
28	A-099	A099/MM14/YG/01/HG/CX	RUFEX-500	Global Pharma Healt	India	65.56	57.43	52.65	66.16	62.13	64.55	61.41	5.34	8.70	Fail
29	A-102	A102/MM14/YG/01/Ocl/C	OETIL	LUPIN LTD.	India	73.42	72.28	70.60	76.05	70.80	69.66	72.14	2.33	3.24	Pass
30	A-104	A104/MM14/YG/02/HP/CX	ZIFTUM 250	ALKEM LABORATOI	India	106.90	103.07	100.65	105.99	99.03	106.29	103.65	3.28	3.16	Pass
32	B-002	B-002/MM14/YG/01/HP/C	ZIFTUM 250	Alkem Laboratories	India	126.66	131.50	131.09	122.42	131.30	136.54	129.92	4.83	3.71	Pass
33	B-003	B-003/MM14/YG/01/HP/C	SPIZEF	Orchid HEALTHCAR	India	98.43	96.21	94.60	92.78	96.41	94.19	95.44	1.99	2.08	Pass
34	B-004	B-004/MM14/YG/01/HP/C	OETIL	LUPIN LTD.	India	73.42	74.84	73.89	75.31	80.48	74.23	75.36	2.60	3.44	Pass
35	B-023	B-023/MM14/YG/07/C/CX	RUFEX	Global Pharma Healt	India	62.33	64.15	62.13	65.36	65.09	63.34	63.73	1.37	2.14	Fail
36	B-027	B-027/MM14/YG/01/C/CX	Zinnat	GlaxoSmithKline	UK	91.77	93.19	89.96	87.74	94.19	93.59	91.74	2.48	2.70	Pass
37	B-029	B-029/MM14/YG/02/C/CX	ZIFTUM 250	Alkem Laboratories	India	80.88	82.50	81.15	89.62	85.12	87.94	84.54	3.65	4.32	Pass
38	B-030	B-030/MM14/YG/08/C/CX	Zinnat	GlaxoSmithKline	UK	89.54	79.58	89.54	84.29	86.06	82.99	85.33	3.89	4.56	Pass
39	B-031	B-031/MM14/YG/08/C/CX	ZIFTUM 250	Alkem Laboratories	India	98.83	97.02	97.42	97.22	101.25	96.41	98.02	1.77	1.81	Pass
40	B-034	B-034/MM14/YG/01/HP/C	ZIFTUM 250	Alkem Laboratories	India	95.14	97.46	98.14	92.41	96.51	96.92	96.10	2.07	2.15	Pass
41	B-038	B-038/MM14/YG/01/HP/C	ZIFTUM 250	Alkem Laboratories	India	127.26	122.02	127.47	124.04	122.09	123.84	124.45	2.41	1.94	Pass
42	B-042	B-042/MM14/YG/01/HG/C	ZIFATIL	Galpha Laboratories	India	88.93	88.31	84.83	87.43	90.36	90.77	88.44	2.16	2.45	Pass
43	B-044	B-044/MM14/YG/01/HG/C	Zinmax	DOMESCO MEDICAL	VietNam	90.77	91.17	92.38	88.55	89.15	89.56	90.26	1.43	1.58	Pass
44	B-047	B-047/MM14/YG/01/C/CX	RUFEX	Global Pharma Healt	India	60.52	59.51	59.71	62.94	60.52	60.32	60.59	1.23	2.03	Fail
45	B-052	B-052/MM14/YG/01/HP/C	OETIL	LUPIN LTD.	India	109.12	107.50	103.74	100.18	112.14	105.89	106.43	4.19	3.93	Pass
46	B-053	B-053/MM14/YG/01/HP/C	Zinnat	GlaxoSmithKline	UK	88.75	94.19	86.13	79.67	74.43	88.35	85.25	7.08	8.31	Pass
47	B-063	B-063/MM14/YG/01/O(e)/	ZIFTUM 250	Alkem Laboratories	India	93.43	88.93	105.52	98.14	93.23	103.13	97.06	6.38	6.57	Pass
48	B-066	B-066/MM14/YG/01/C/CX	ZIFTUM 250	Alkem Laboratories	India	91.59	87.90	96.92	95.69	94.25	100.60	94.49	4.39	4.65	Pass
49	B-067	B-067/MM14/YG/01/C/CX	RUFEX-250	Global Pharma Healt	India	84.92	72.82	78.46	81.96	77.66	79.67	79.25	4.10	5.18	Pass
50	B-076	B-076/MM14/YG/01/HG/C	ZIFTUM 250	Alkem Laboratories	India	99.23	92.98	93.99	95.60	94.19	96.21	95.37	2.22	2.33	Pass
51	B-079	B-079/MM14/YG/01/O(e)/	ZIFTUM 250	Alkem Laboratories	India	93.39	93.99	90.36	91.57	92.98	95.47	92.96	1.80	1.94	Pass
52	B-080	B-080/MM14/YG/01/O(e)/	Zinnat	GlaxoSmithKline	UK	91.37	89.76	83.10	91.77	86.33	90.97	88.88	3.45	3.88	Pass
53	B-086	B-086/MM14/YG/03/C/CX	Zinnat	GlaxoSmithKline	UK	77.26	88.61	85.19	80.88	82.50	81.15	82.60	3.91	4.73	Pass
54	B-089	B-089/MM14/YG/04/W/CX	Zinnat	GlaxoSmithKline	UK	77.66	89.89	75.64	81.69	73.02	78.67	79.43	5.89	7.42	Pass
55	B-093	B-093/MM14/YG/01/C/CX	RUFEX	Global Pharma Healt	India	65.56	64.75	87.54	85.12	81.49	89.76	79.04	11.10	14.04	Fail
56	B-100	B-100/MM14/YG/04/C/CX	ZIFTUM 250	Alkem Laboratories	India	100.04	98.43	100.04	98.83	96.41	102.06	99.30	1.90	1.91	Pass
57	B-101	B-101/MM14/YG/05/C/CX	Zinnat	GlaxoSmithKline	UK	89.15	85.52	92.51	88.35	89.15	91.17	89.31	2.41	2.70	Pass
58	B-102	B-102/MM14/YG/02/C/CX	Zinnat	GlaxoSmithKline	UK	83.91	89.62	87.81	88.28	95.60	91.37	89.43	3.91	4.37	Pass
59	B-104	B104/MM14/YG/01/HG/CX	ZIFTUM 250	Alkem Laboratories	India	94.80	98.23	90.36	93.99	96.01	92.18	94.26	2.78	2.95	Pass
60	B-111	B111/MM14/YG/02/C/CXM	RUFEX-250	Global Pharma Healt	India	76.91	67.63	74.18	89.13	89.13	85.99	80.50	8.92	11.08	Pass
1	PA-001	PA001/MM14/YG/01/C/CX	ZIFTUM 250	Alkem Laboratories L	India	158.05	134.52	153.14	152.94	136.54	146.22	146.90	9.60	6.53	Pass
2	PA-002	PA002/MM14/YG/01/C/CX	SPIZEF	Orchid HEALTHCAR	India	73.83	98.97	100.24	97.22	85.79	83.04	89.85	10.63	11.83	Pass
31	PB-001	PB-001/MM14/YG/01/O(e)	ZINNASAV-250	SAVIOUR PHARMAC	India	75.96	82.78	83.19	85.86	82.56	81.35	81.95	3.29	4.02	Pass

Dissolution test for first stage (cont'd)

Serial No.	Sample Code	Trade name of the product	Name of Manufacturer	Manufacturing Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge at 45 分	Final Judge
A-005	A005/MM14/	SPIZEF	Orchid HEAL	India	97.95	96.71	96.10	96.71	99.30	95.48	97.04	1.38	1.42	Pass	Pass
A-006	A006/MM14/	Zinnat	GlaxoSmithKl	UK	94.60	103.07	95.00	96.41	100.44	100.65	98.36	3.49	3.55	Pass	Pass
A-007	A007/MM14/	ZIFTUM 250	Alkem Labora	India	99.23	107.50	106.29	107.91	104.68	105.28	105.15	3.15	3.00	Pass	Pass
A-016	A016/MM14/	ZINNASAV-2	SAVIOUR PH	India	94.40	95.20	88.14	85.52	95.20	87.14	90.93	4.47	4.92	Pass	Pass
A-017	A017/MM14/	ZIFATIL-250	Galpha Labor	India	116.37	109.32	111.27	108.17	112.27	115.97	112.23	3.38	3.01	Pass	Pass
A-018	A018/MM14/	CETIL	LUPIN LTD.	India	108.38	100.40	100.19	104.49	101.83	102.04	102.89	3.10	3.01	Pass	Pass
A-019	A019/MM14/	FUROCEF	RENATA LIM	Bangladesh	80.88	86.53	87.54	100.51	100.85	92.58	91.48	8.04	8.78	Pass	Pass
A-025	A025/MM14/	SPIZEF	Orchid HEAL	India	97.55	100.85	92.98	81.29	97.82	96.01	94.42	6.92	7.33	Pass	Pass
A-030	A030/MM14/	RUFEX-250	Global Pharm	India	91.57	91.57	76.25	93.05	90.97	93.79	89.53	6.59	7.36	Pass	Fail
A-036	A036/MM14/	ZIFTUM 250	Alkem Labora	India	106.13	101.56	94.05	102.24	103.26	101.22	101.41	4.02	3.96	Pass	Pass
A-037	A037/MM14/	Cefusan 250	SRS pharmac	India	96.92	100.26	97.94	98.76	104.70	97.80	99.40	2.83	2.85	Pass	Pass
A-048	A048/MM14/	RUFEX-250	Global Pharm	India	85.93	87.54	85.72	85.93	88.14	88.82	87.01	1.33	1.53	Pass	Fail
A-052	A052/MM14/	ZIFTUM 250	Alkem Labora	India	102.86	101.65	107.77	101.92	107.17	103.13	104.09	2.69	2.58	Pass	Pass
A-054	A054/MM14/	ZIFTUM 250	Alkem Labora	India	105.28	106.90	101.86	105.69	103.67	104.48	104.65	1.75	1.67	Pass	Pass
A-057	A057/MM14/	RUFEX-250	Global Pharm	India	79.03	83.19	81.56	85.65	90.91	84.01	84.06	4.04	4.81	Fail	Fail
A-058	A058/MM14/	Zinnat	GlaxoSmithKl	UK	101.25	101.65	98.43	98.02	102.06	100.04	100.24	1.71	1.70	Pass	Pass
A-063	A063/MM14/	ZIFTUM 250	ALKEM LABO	India	109.41	100.33	99.17	97.53	106.13	102.24	102.47	4.51	4.40	Pass	Pass
A-068	A068/MM14/	RUFEX-250	Global Pharm	India	85.93	75.44	89.35	91.57	91.37	91.37	86.62	6.01	6.93	Fail	Fail
A-071	A071/MM14/	ZIFTUM 250	ALKEM LABO	India	102.86	101.86	92.51	103.67	97.82	102.86	100.27	4.33	4.32	Pass	Pass
A-074	A074/MM14/	ZIFTUM 250	ALKEM LABO	India	100.04	90.77	95.81	96.21	93.79	93.79	96.08	3.56	3.71	Pass	Pass
A-079	A079/MM14/	RUFEX-250	Global Pharm	India	77.05	83.44	73.29	86.73	69.79	75.64	77.66	6.34	8.17	Fail	Fail
A-085	A085/MM14/	RUFEX-250	Global Pharm	India	86.47	78.89	91.18	79.23	84.22	90.57	85.09	5.34	6.27	Fail	Fail
A-086	A086/MM14/	Zinnat	GlaxoSmithKl	UK	96.21	96.81	99.84	99.71	98.02	96.28	97.81	1.65	1.69	Pass	Pass
A-089	A089/MM14/	Cefotil	SQUARE PH	Bangladesh	90.56	93.19	91.57	94.80	96.41	95.81	93.72	2.35	2.51	Pass	Pass
A-095	A095/MM14/	KEFROX	CCL Pharmac	Pakistan	97.29	98.36	100.04	100.31	91.17	93.39	96.76	3.71	3.84	Pass	Pass
A-099	A099/MM14/	RUFEX-500	Global Pharm	India	84.72	83.91	84.51	86.93	82.09	86.26	84.74	1.72	2.04	Pass	Fail
A-102	A102/MM14/	CETIL	LUPIN LTD.	India	99.44	93.39	98.23	99.44	94.80	96.41	96.95	2.51	2.59	Pass	Pass
A-104	A104/MM14/	ZIFTUM 250	ALKEM LABO	India	107.70	105.82	106.70	118.19	102.66	110.80	108.64	5.37	4.94	Pass	Pass
B-002	B-002/MM14	ZIFTUM 250	Alkem Labora	India	117.58	121.01	117.18	119.40	115.16	118.93	118.21	2.03	1.71	Pass	Pass
B-003	B-003/MM14	SPIZEF	Orchid HEAL	India	101.45	97.02	95.20	99.84	97.62	100.24	98.56	2.34	2.37	Pass	Pass
B-004	B-004/MM14	CETIL	LUPIN LTD.	India	98.56	93.79	87.94	95.00	99.44	97.02	95.29	4.18	4.38	Pass	Pass
B-023	B-023/MM14	RUFEX	Global Pharm	India	82.90	84.31	81.49	81.29	84.31	89.56	83.98	3.03	3.61	Pass	Fail
B-027	B-027/MM14	Zinnat	GlaxoSmithKl	UK	100.24	104.95	98.83	97.96	100.65	100.44	100.51	2.41	2.40	Pass	Pass
B-029	B-029/MM14	ZIFTUM 250	Alkem Labora	India	104.88	97.82	104.28	103.87	104.88	102.33	103.01	2.71	2.63	Pass	Pass
B-030	B-030/MM14	Zinnat	GlaxoSmithKl	UK	97.32	96.92	97.73	96.10	95.48	95.28	96.47	1.01	1.04	Pass	Pass
B-031	B-031/MM14	ZIFTUM 250	Alkem Labora	India	104.48	125.11	103.47	107.91	125.45	103.67	111.68	10.66	9.54	Pass	Pass
B-034	B-034/MM14	ZIFTUM 250	Alkem Labora	India	100.40	105.31	105.31	99.10	98.28	101.01	101.57	3.05	3.01	Pass	Pass
B-038	B-038/MM14	ZIFATIL	Galpha Labor	India	119.20	123.03	124.24	116.58	119.00	112.54	119.10	4.27	3.59	Pass	Pass
B-042	B-042/MM14	ZIFATIL	Galpha Labor	India	92.00	97.53	92.41	93.16	92.82	99.37	94.55	3.10	3.28	Pass	Pass
B-044	B-044/MM14	Zinmax	DOMESCO M	VietNam	102.06	105.08	99.84	101.52	100.78	100.38	101.61	1.88	1.85	Pass	Pass
B-047	B-047/MM14	RUFEX	Global Pharm	India	83.04	80.48	85.93	83.71	81.02	81.89	82.68	2.00	2.41	Pass	Fail
B-052	B-052/MM14	CETIL	LUPIN LTD.	India	108.31	105.89	102.06	107.30	106.16	100.85	105.09	2.97	2.83	Pass	Pass
B-053	B-053/MM14	Zinnat	GlaxoSmithKl	UK	102.66	106.09	95.00	95.00	91.44	96.21	97.73	5.50	5.62	Pass	Pass
B-063	B-063/MM14	ZIFTUM 250	Alkem Labora	India	101.83	95.28	112.89	103.06	116.58	110.57	106.70	7.98	7.48	Pass	Pass
B-066	B-066/MM14	ZIFTUM 250	Alkem Labora	India	96.30	96.44	107.22	103.06	105.52	108.73	102.88	5.38	5.23	Pass	Pass
B-067	B-067/MM14	RUFEX-250	Global Pharm	India	97.15	90.77	94.60	96.01	93.99	96.81	94.89	2.37	2.49	Pass	Pass
B-076	B-076/MM14	ZIFTUM 250	Alkem Labora	India	108.51	103.67	105.69	108.11	83.10	104.81	102.32	9.60	9.38	Pass	Pass
B-079	B-079/MM14	ZIFTUM 250	Alkem Labora	India	105.89	102.66	100.04	101.25	102.86	104.68	102.90	2.15	2.09	Pass	Pass
B-080	B-080/MM14	Zinnat	GlaxoSmithKl	UK	101.18	98.23	95.00	108.17	96.41	100.65	99.94	4.68	4.69	Pass	Pass
B-086	B-086/MM14	Zinnat	GlaxoSmithKl	UK	90.97	98.02	99.37	94.40	88.75	97.29	94.80	4.22	4.45	Pass	Pass
B-089	B-089/MM14	Zinnat	GlaxoSmithKl	UK	93.79	101.25	97.89	100.04	94.40	97.62	97.50	2.97	3.05	Pass	Pass
B-093	B-093/MM14	RUFEX	Global Pharm	India	71.47	72.62	94.73	91.50	87.34	91.57	84.87	10.22	12.04	Fail	Fail
B-100	B-100/MM14	ZIFTUM 250	Alkem Labora	India	104.28	100.04	103.13	103.27	103.67	108.11	103.75	2.59	2.50	Pass	Pass
B-101	B-101/MM14	Zinnat	GlaxoSmithKl	UK	102.53	97.82	97.82	99.30	82.50	100.11	96.68	7.16	7.41	Pass	Pass
B-102	B-102/MM14	Zinnat	GlaxoSmithKl	UK	97.02	102.60	99.44	99.03	85.12	98.02	96.87	6.06	6.25	Pass	Pass
B-104	B104/MM14/	ZIFTUM 250	Alkem Labora	India	103.81	108.71	101.45	102.26	107.30	97.62	103.53	4.05	3.91	Pass	Pass
B-111	B111/MM14/	RUFEX-250	Global Pharm	India	86.06	85.86	90.16	91.80	91.39	89.35	2.68	3.00	Pass	Pass	Pass
PA-001	PA001/MM14	ZIFTUM 250	Alkem Labora	India	125.25	126.12	123.63	124.24	117.18	120.61	122.84	3.35	2.73	Pass	Pass
PA-002	PA002/MM14	SPIZEF	Orchid HEAL	India	79.81	100.23	100.71	99.97	87.07	85.32	92.19	9.21	10.00	Fail	Fail
PB-001	PB-001/MM1	ZINNASAV-2	SAVIOUR PH	India	79.44	91.18	90.57	89.95	86.47	90.02	87.94	4.48	5.09	Fail	Fail

Dissolution test 6 tablets for second stage:

Serial No.	Sample Code	Trade name of the product	Name of Manufacturer	Manufacturing Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge at 15 分
A-005	A005/MM14/	SPIZEF	Orchid HEAL	India										
A-006	A006/MM14/	Zinnat	GlaxoSmithKl	UK										
A-007	A007/MM14/	ZIFTUM 250	Alkem Labora	India										
A-016	A016/MM14/	ZINNASAV-2	SAVIOUR PH	India										
A-017	A017/MM14/	ZIFATIL-250	Galpha Labor	India										
A-018	A018/MM14/	CETIL	LUPIN LTD.	India										
A-019	A019/MM14/	FUROCEF	RENATA LIM	Bangladesh										
A-025	A025/MM14/	SPIZEF	Orchid HEAL	India										
A-030	A030/MM14/	RUFEX-250	Global Pharm	India	84.72	82.50	89.96	88.55	89.35	87.74	82.33	8.70	10.56	pass
A-036	A036/MM14/	ZIFTUM 250	Alkem Labora	India										
A-037	A037/MM14/	Cefusan 250	SRS pharmac	India										
A-048	A048/MM14/	RUFEX-250	Global Pharm	India	50.91	68.38	63.41	62.47	61.93	67.37	64.39	4.81	7.47	pass
A-052	A052/MM14/	ZIFTUM 250	Alkem Labora	India										
A-054	A054/MM14/	ZIFTUM 250	Alkem Labora	India										
A-057	A057/MM14/	RUFEX-250	Global Pharm	India	72.21	74.57	87.67	44.39	64.22	71.21	70.08	12.00	17.13	Fail
A-058	A058/MM14/	Zinnat	GlaxoSmithKl	UK										
A-063	A063/MM14/	ZIFTUM 250	ALKEM LABO	India										
A-068	A068/MM14/	RUFEX-250	Global Pharm	India	—	—	—	—	—	—	—	—	—	—
A-071	A071/MM14/	ZIFTUM 250	ALKEM LABO	India										
A-074	A074/MM14/	ZIFTUM 250	ALKEM LABO	India										
A-079	A079/MM14/	RUFEX-250	Global Pharm	India	—	—	—	—	—	—	—	—	—	—
A-085	A085/MM14/	RUFEX-250	Global Pharm	India	67.04	63.95	61.33	62.33	61.73	58.70	63.23	3.57	5.64	pass
A-086	A086/MM14/	Zinnat	GlaxoSmithKl	UK										
A-089	A089/MM14/	Cefotil	SQUARE PH	Bangladesh										
A-095	A095/MM14/	KEFROX	COL Pharmac	Pakistan										
A-099	A099/MM14/	RUFEX-500	Global Pharm	India	67.17	73.96	75.44	68.18	69.46	76.25	66.58	7.01	10.53	pass
A-102	A102/MM14/	CETIL	LUPIN LTD.	India										
A-104	A104/MM14/	ZIFTUM 250	ALKEM LABO	India										
B-002	B-002/MM14	ZIFTUM 250	Alkem Labora	India										
B-003	B-003/MM14	SPIZEF	Orchid HEAL	India										
B-004	B-004/MM14	CETIL	LUPIN LTD.	India										
B-023	B-023/MM14	RUFEX	Global Pharm	India										
B-027	B-027/MM14	Zinnat	GlaxoSmithKl	UK										
B-029	B-029/MM14	ZIFTUM 250	Alkem Labora	India										
B-030	B-030/MM14	Zinnat	GlaxoSmithKl	UK										
B-031	B-031/MM14	ZIFTUM 250	Alkem Labora	India										
B-034	B-034/MM14	ZIFTUM 250	Alkem Labora	India										
B-038	B-038/MM14	ZIFTUM 250	Alkem Labora	India										
B-042	B-042/MM14	ZIFATIL	Galpha Labor	India										
B-044	B-044/MM14	Zinmax	DOMESCO M	VietNam										
B-047	B-047/MM14	RUFEX	Global Pharm	India										
B-052	B-052/MM14	CETIL	LUPIN LTD.	India										
B-053	B-053/MM14	Zinnat	GlaxoSmithKl	UK										
B-063	B-063/MM14	ZIFTUM 250	Alkem Labora	India										
B-066	B-066/MM14	ZIFTUM 250	Alkem Labora	India										
B-067	B-067/MM14	RUFEX-250	Global Pharm	India										
B-076	B-076/MM14	ZIFTUM 250	Alkem Labora	India										
B-079	B-079/MM14	ZIFTUM 250	Alkem Labora	India										
B-080	B-080/MM14	Zinnat	GlaxoSmithKl	UK										
B-086	B-086/MM14	Zinnat	GlaxoSmithKl	UK										
B-089	B-089/MM14	Zinnat	GlaxoSmithKl	UK										
B-093	B-093/MM14	RUFEX	Global Pharm	India	—	—	—	—	—	—	—	—	—	—
B-100	B-100/MM14	ZIFTUM 250	Alkem Labora	India										
B-101	B-101/MM14	Zinnat	GlaxoSmithKl	UK										
B-102	B-102/MM14	Zinnat	GlaxoSmithKl	UK										
B-104	B104/MM14/	ZIFTUM 250	Alkem Labora	India										
B-111	B111/MM14/	RUFEX-250	Global Pharm	India										
PA-001	PA001/MM14	ZIFTUM 250	Alkem Labora	India										
PA-002	PA002/MM14	SPIZEF	Orchid HEAL	India	93.99	86.73	105.49	96.81	85.59	101.25	92.41	9.31	10.08	pass
PB-001	PB-001/MM1	ZINNASAV-2	SAVIOUR PH	India	87.20	80.48	83.51	83.10	89.96	84.04	83.33	3.48	4.18	pass

Dissolution test for second stage (cont'd):

Serial No.	Sample Code	Trade name of the product	Name of Manufacturer & Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge at 45 分	Judge for Dissolution
A-005	A005/MM14/	SPIZEF	Orchid HEAL'India											Pass
A-006	A006/MM14/	Zinnat	GlaxoSmithKl UK											Pass
A-007	A007/MM14/	ZIFTUM 250	Alkem Labora India											Pass
A-016	A016/MM14/	ZINNASAV-2	SAVIOUR PH India											Pass
A-017	A017/MM14/	ZIFATIL-250	Galpha Labor India											Pass
A-018	A018/MM14/	CETIL	LUPIN LTD. India											Pass
A-019	A019/MM14/	FUROCEF	RENATA LIM Bangladesh											Pass
A-025	A025/MM14/	SPIZEF	Orchid HEAL'India											Pass
A-030	A030/MM14/	RUFEX-250	Global Pharm India	93.19	83.64	97.62	93.79	95.00	93.39	91.15	5.74	6.30	pass	Pass
A-036	A036/MM14/	ZIFTUM 250	Alkem Labora India											Pass
A-037	A037/MM14/	Cefusan 250	SRS pharmac India											Pass
A-048	A048/MM14/	RUFEX-250	Global Pharm India	82.70	88.55	85.32	84.72	81.36	87.94	86.05	2.33	2.71	pass	Pass
A-052	A052/MM14/	ZIFTUM 250	Alkem Labora India											Pass
A-054	A054/MM14/	ZIFTUM 250	Alkem Labora India											Pass
A-057	A057/MM14/	RUFEX-250	Global Pharm India	75.78	83.04	96.21	61.33	67.64	74.70	80.25	9.53	11.88	pass	Fail
A-058	A058/MM14/	Zinnat	GlaxoSmithKl UK											Pass
A-063	A063/MM14/	ZIFTUM 250	ALKEM LABO India											Pass
A-068	A068/MM14/	RUFEX-250	Global Pharm India	—	—	—	—	—	—	—	—	—	—	Fail
A-071	A071/MM14/	ZIFTUM 250	ALKEM LABO India											Pass
A-074	A074/MM14/	ZIFTUM 250	ALKEM LABO India											Pass
A-079	A079/MM14/	RUFEX-250	Global Pharm India	—	—	—	—	—	—	—	—	—	—	Fail
A-085	A085/MM14/	RUFEX-250	Global Pharm India	82.63	87.00	83.91	85.12	85.93	79.88	84.59	4.03	4.76	pass	Pass
A-086	A086/MM14/	Zinnat	GlaxoSmithKl UK											Pass
A-089	A089/MM14/	Cefotil	SQUARE PH/ Bangladesh											Pass
A-095	A095/MM14/	KEFROX	COL Pharmac Pakistan											Pass
A-099	A099/MM14/	RUFEX-500	Global Pharm India	86.80	101.59	90.77	82.30	90.23	91.98	87.67	5.43	6.19	pass	Pass
A-102	A102/MM14/	CETIL	LUPIN LTD. India											Pass
A-104	A104/MM14/	ZIFTUM 250	ALKEM LABO India											Pass
B-002	B-002/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-003	B-003/MM14	SPIZEF	Orchid HEAL'India											Pass
B-004	B-004/MM14	CETIL	LUPIN LTD. India											Pass
B-023	B-023/MM14	RUFEX	Global Pharm India											Fail
B-027	B-027/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-029	B-029/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-030	B-030/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-031	B-031/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-034	B-034/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-038	B-038/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-042	B-042/MM14	ZIFATIL	Galpha Labor India											Pass
B-044	B-044/MM14	Zinmax	DOMESCO M VietNam											Pass
B-047	B-047/MM14	RUFEX	Global Pharm India											Fail
B-052	B-052/MM14	CETIL	LUPIN LTD. India											Pass
B-053	B-053/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-063	B-063/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-066	B-066/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-067	B-067/MM14	RUFEX-250	Global Pharm India											Pass
B-076	B-076/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-079	B-079/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-080	B-080/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-086	B-086/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-089	B-089/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-093	B-093/MM14	RUFEX	Global Pharm India	-	-	-	-	-	-	-	-	-	-	Fail
B-100	B-100/MM14	ZIFTUM 250	Alkem Labora India											Pass
B-101	B-101/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-102	B-102/MM14	Zinnat	GlaxoSmithKl UK											Pass
B-104	B104/MM14/	ZIFTUM 250	Alkem Labora India											Pass
B-111	B111/MM14/	RUFEX-250	Global Pharm India											Pass
PA-001	PA001/MM14	ZIFTUM 250	Alkem Labora India											Pass
PA-002	PA002/MM14	SPIZEF	Orchid HEAL'India	96.41	86.93	105.69	99.44	90.56	103.27	94.62	8.31	8.78	pass	Pass
PB-001	PB-001/MM1	ZINNASAV-2	SAVIOUR PH India	92.78	84.31	91.37	88.55	100.24	90.97	89.65	4.99	5.57	pass	Pass

Result of quantity test and content uniformity test [OM] 1st stage- BP

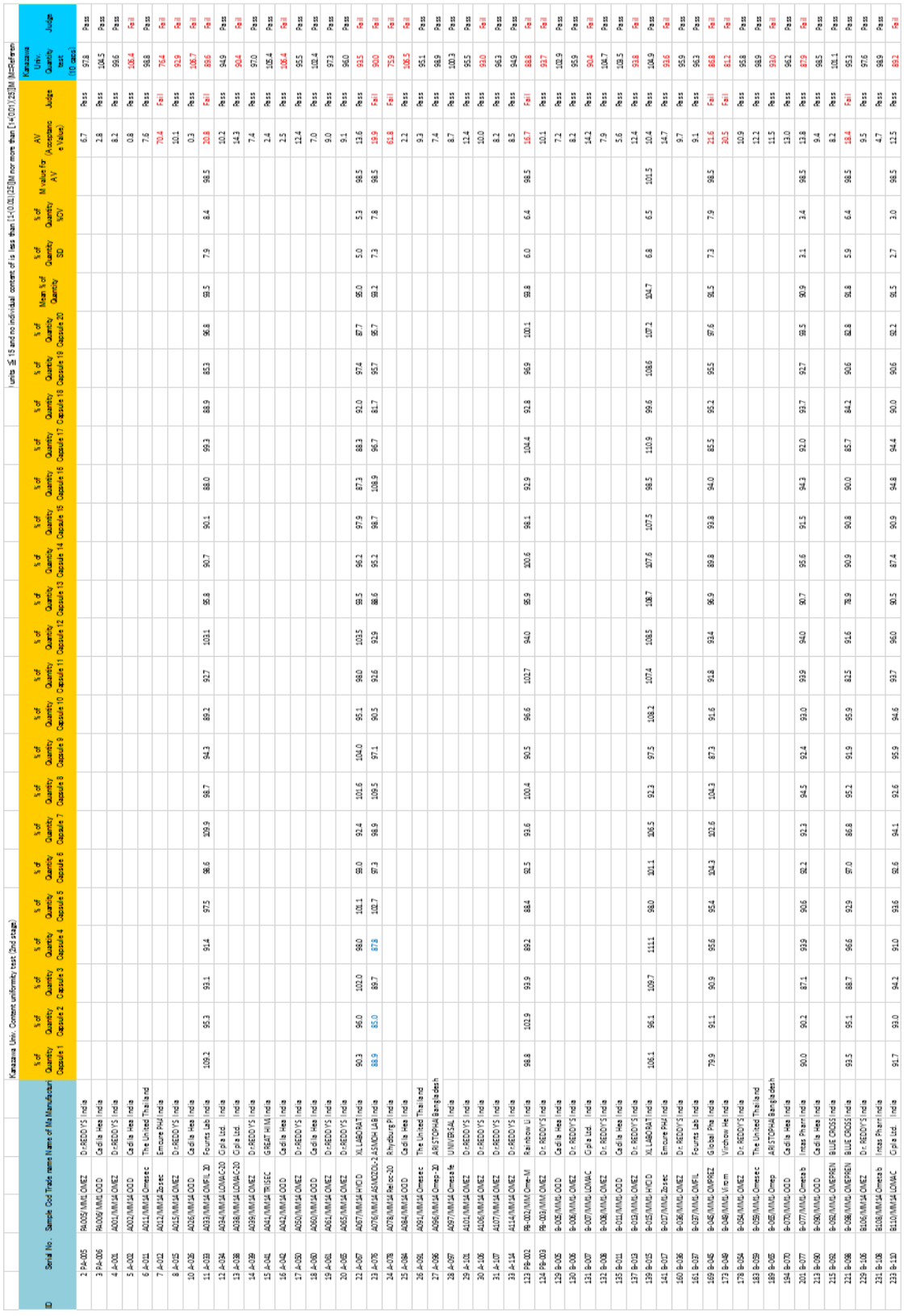
			Kanazawa Univ. Content uniformity test (1st stage)						tolerance: AV≦150								BP 950≦mean≦105	
ID	Serial No.	Sample Code	% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	% of Quantity Capsule 7	% of Quantity Capsule 8	% of Quantity Capsule 9	% of Quantity Capsule 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge	Mean % of Quantity	Judge
27	A-096	A096/MM14/YG/	98.4	103.4	96.8	103.9	100.1	99.0	94.2	99.7	98.1	95.7	98.9	3.1	3.1	7.4	Pass	98.9	Pass
189	B-065	B-065/MM14/YG/	90.5	91.9	91.6	95.1	95.2	96.6	91.0	90.8	91.1	96.5	93.0	2.5	2.7	11.5	Pass	93.0	Fail
23	A-076	A076/MM14/YG/	88.2	87.8	86.7	97.1	83.7	84.2	88.3	93.3	85.2	105.7	90.0	6.9	7.6	25.0	Fail	90.0	Fail
215	B-092	B-092/MM14/YG/	99.9	103.1	98.4	102.9	105.9	94.3	102.8	101.5	98.1	103.8	101.1	3.4	3.4	8.2	Pass	101.1	Pass
221	B-098	B-098/MM14/YG/	97.5	95.4	81.2	90.8	100.2	98.4	100.1	94.5	93.9	101.2	95.3	6.0	6.2	17.5	Fail	95.3	Pass
129	B-005	B-005/MM14/YG/	99.1	108.0	100.1	99.8	99.6	106.5	103.0	100.4	104.1	107.9	102.9	3.6	3.5	7.2	Pass	102.9	Pass
135	B-011	B-011/MM14/YG/	102.7	102.6	105.7	101.5	96.8	106.0	106.1	105.5	101.0	106.7	103.5	3.1	3.0	5.6	Pass	103.5	Pass
194	B-070	B-070/MM14/YG/	95.9	94.0	97.5	91.8	91.4	90.8	99.0	100.9	96.1	104.8	96.2	4.5	4.7	13.0	Pass	96.2	Pass
213	B-090	B-090/MM14/YG/	97.1	94.1	95.2	100.0	99.5	100.9	92.6	105.0	97.8	102.7	98.5	3.9	4.0	9.4	Pass	98.5	Pass
3	PA-006	PA006/MM14/YG	107.7	105.9	104.9	101.8	99.9	104.6	103.2	104.3	107.8	105.1	104.5	2.4	2.3	2.8	Pass	104.5	Pass
5	A-002	A002/MM14/YG/	101.6	106.5	107.0	106.7	106.5	105.2	106.5	104.5	109.7	109.8	106.4	2.4	2.2	0.8	Pass	106.4	Fail
10	A-026	A026/MM14/YG/	101.4	106.5	106.8	106.7	106.5	105.1	107.9	107.4	109.2	109.7	106.7	2.3	2.2	0.3	Pass	106.7	Fail
16	A-042	A042/MM14/YG/	99.5	107.6	104.4	106.9	104.4	109.8	107.9	109.4	108.3	105.4	106.4	3.1	2.9	2.5	Pass	106.4	Fail
18	A-060	A060/MM14/YG/	99.6	108.0	99.8	98.9	106.3	105.3	104.0	99.5	100.2	102.9	102.4	3.3	3.2	7.0	Pass	102.4	Pass
25	A-084	A084/MM14/YG/	99.8	107.9	104.5	107.2	104.5	109.8	107.8	109.6	108.4	105.8	106.5	3.0	2.8	2.2	Pass	106.5	Fail
12	A-034	A034/MM14/YG/	91.1	91.6	92.7	97.9	99.0	97.1	94.9	96.7	93.7	93.8	94.9	2.7	2.9	10.2	Pass	94.9	Pass
13	A-038	A038/MM14/YG/	89.8	92.1	89.0	88.8	90.8	93.0	92.2	93.5	90.0	84.7	90.4	2.6	2.9	14.3	Pass	90.4	Fail
131	B-007	B-007/MM14/YG/	89.8	92.1	89.1	88.9	91.0	93.0	92.3	93.5	89.9	84.8	90.4	2.6	2.9	14.2	Pass	90.4	Fail
233	B-110	B110/MM14/YG/	87.9	89.2	89.3	87.9	90.6	87.9	88.6	85.5	91.0	93.8	89.2	2.2	2.5	5.4	Pass	89.2	Fail
124	PB-003	PB-003/MM14/Y(	92.1	96.0	90.3	91.2	92.0	95.0	94.2	93.6	95.9	96.5	93.7	2.2	2.3	10.1	Pass	93.7	Fail
130	B-006	B-006/MM14/YG/	96.4	94.7	95.8	91.6	97.6	92.5	97.6	96.6	98.5	98.0	95.9	2.3	2.4	8.2	Pass	95.9	Pass
132	B-008	B-008/MM14/YG/	102.0	95.8	110.0	107.2	107.8	108.5	106.7	98.2	105.6	105.3	104.7	4.6	4.4	7.9	Pass	104.7	Pass
137	B-013	B-013/MM14/YG/	90.7	95.5	93.6	91.0	99.3	90.8	96.0	91.3	98.0	91.7	93.8	3.2	3.4	12.4	Pass	93.8	Fail
160	B-036	B-036/MM14/YG/	96.2	97.8	99.7	95.8	98.9	94.6	93.0	93.6	98.6	90.6	95.9	2.9	3.1	9.7	Pass	95.9	Pass
178	B-054	B-054/MM14/YG/	93.5	94.2	102.0	93.3	96.1	93.1	98.5	100.9	92.9	93.8	95.8	3.4	3.6	10.9	Pass	95.8	Pass
229	B-106	B106/MM14/YG/	98.9	93.0	95.9	96.4	100.3	99.5	92.0	96.3	100.5	103.6	97.6	3.6	3.7	9.5	Pass	97.6	Pass
2	PA-005	PA005/MM14/YG	96.3	101.6	92.5	98.5	99.4	96.6	97.9	96.6	100.0	98.2	97.8	2.5	2.5	6.7	Pass	97.8	Pass
4	A-001	A001/MM14/YG/	101.2	94.0	105.6	98.6	101.9	98.5	95.0	95.6	102.6	102.7	99.6	3.8	3.9	8.2	Pass	99.6	Pass
8	A-015	A015/MM14/YG/	90.0	90.9	92.3	92.2	95.9	95.4	92.5	94.4	93.4	92.2	92.9	1.9	2.0	10.1	Pass	92.9	Fail
14	A-039	A039/MM14/YG/	93.2	98.1	96.6	99.7	95.5	94.3	97.0	97.2	96.9	101.7	97.0	2.5	2.5	7.4	Pass	97.0	Pass
17	A-050	A050/MM14/YG/	90.1	95.5	92.5	95.0	96.7	103.7	98.3	90.8	95.4	97.0	95.5	3.9	4.1	12.4	Pass	95.5	Pass
19	A-061	A061/MM14/YG/	92.1	102.4	99.3	96.7	92.8	98.1	95.1	100.4	98.0	98.5	97.3	3.3	3.4	9.0	Pass	97.3	Pass
20	A-065	A065/MM14/YG/	92.3	94.7	98.9	100.1	99.6	95.7	93.9	95.3	92.7	97.2	96.0	2.8	2.9	9.1	Pass	96.0	Pass
29	A-101	A101/MM14/YG/	95.2	90.3	96.8	103.7	95.0	92.6	98.2	90.7	95.9	97.1	95.5	3.9	4.1	12.4	Pass	95.5	Pass
30	A-106	A106/MM14/YG/	92.5	92.6	96.1	92.2	92.3	90.0	91.1	93.6	94.5	95.4	93.0	1.9	2.0	10.0	Pass	93.0	Fail
31	A-107	A107/MM14/YG/	94.8	92.6	97.8	98.2	97.0	92.0	98.3	96.7	99.3	96.0	96.3	2.5	2.6	8.2	Pass	96.3	Pass
33	A-114	A114/MM14/YG/	97.1	93.7	96.7	97.7	94.0	93.4	94.0	96.9	91.6	93.9	94.9	2.0	2.1	8.5	Pass	94.9	Pass
7	A-012	A012/MM14/YG/	56.5	47.1	95.7	99.2	77.9	47.6	83.0	72.5	85.2	99.6	76.4	20.1	26.4	70.4	Fail	76.4	Fail
141	B-017	B-017/MM14/YG/	89.0	91.5	96.7	95.8	98.8	100.1	88.1	90.3	93.3	92.7	93.6	4.1	4.4	14.7	Pass	93.6	Fail
161	B-037	B-037/MM14/YG/	92.4	93.0	94.0	99.5	100.6	98.6	96.3	98.2	94.8	95.2	96.3	2.8	3.0	9.1	Pass	96.3	Pass
11	A-033	A033/MM14/YG/	75.6	84.7	81.9	86.5	101.0	80.1	99.1	100.1	95.9	91.3	89.6	9.1	10.2	30.8	Fail	89.6	Fail
169	B-045	B-045/MM14/YG/	93.0	78.3	77.4	76.2	89.1	94.1	91.4	97.8	82.9	87.6	86.8	7.7	8.8	30.1	Fail	86.8	Fail
15	A-041	A041/MM14/YG/	109.2	107.2	107.9	106.3	102.1	105.1	104.5	105.3	106.4	100.3	105.4	2.7	2.5	2.4	Pass	105.4	Pass
201	B-077	B-077/MM14/YG/	86.1	91.8	87.7	83.8	90.4	86.5	88.2	89.4	84.2	90.7	87.9	2.7	3.1	17.2	Fail	87.9	Fail
231	B-108	B108/MM14/YG/	101.2	101.4	98.2	99.3	96.9	96.9	98.6	96.0	99.1	101.5	98.9	2.0	2.0	4.7	Pass	98.9	Pass
123	PB-002	PB-002/MM14/Y(	90.9	81.7	99.9	92.7	93.5	85.0	85.6	87.3	85.5	86.5	88.8	5.4	6.0	22.5	Fail	88.8	Fail
24	A-078	A078/MM14/YG/	99.8	94.0	62.2	62.5	76.6	45.5	73.8	90.3	76.0	78.7	75.9	16.4	21.5	61.8	Fail	75.9	Fail
6	A-011	A011/MM14/YG/	100.0	93.9	99.7	95.4	96.7	97.9	98.4	98.9	104.0	103.3	98.8	3.2	3.2	7.6	Pass	98.8	Pass
26	A-091	A091/MM14/YG/	93.3	94.5	96.5	91.2	96.4	95.7	93.8	92.6	98.3	98.7	95.1	2.4	2.6	9.3	Pass	95.1	Pass
183	B-059	B-059/MM14/YG/	98.3	90.0	97.8	90.3	99.0	101.3	101.6	104.2	103.4	103.3	98.9	5.1	5.2	12.2	Pass	98.9	Pass
28	A-097	A097/MM14/YG/	94.1	103.4	99.3	101.9	96.4	104.2	97.3	103.5	98.6	104.0	100.3	3.6	3.6	8.7	Pass	100.3	Pass
173	B-049	B-049/MM14/YG/	80.6	69.2	77.8	80.0	89.5	78.4	85.0	85.6	82.6	83.4	81.2	5.5	6.8	30.5	Fail	81.2	Fail
139	B-015	B-015/MM14/YG/	98.6	113.1	90.3	98.3	116.2	96.6	100.7	108.9	113.3	113.5	104.9	9.1	8.6	18.3	Fail	104.9	Pass
22	A-067	A067/MM14/YG/	88.1	99.5	100.1	94.7	95.0	89.9	98.0	87.3	90.8	91.6	93.5	4.7	5.0	16.2	Fail	93.5	Fail

Result of quantity test and content uniformity test [OM] 1st stage- USP

USP Samples

						Kanazawa Univ. Content uniformity test (1st stage)																
1	PA-004	PA004/MM1	OMAC	MDC PHARM	India	90.1	104.8	101.3	101.7	97.1	108.1	100.5	102.6	99.5	103.5	100.9	4.8	4.8	11.6	Pass	100.9	Pass
9	A-021	A021/MM14	OMAPIN-20	BRAWN LAB	India	93.7	98.7	97.3	93.1	102.3	101.1	92.4	93.3	90.7	107.7	97.0	5.4	5.6	14.4	Pass	97.0	Pass
21	A-066	A066/MM14	OMAC	MDC PHARM	India	100.0	94.7	101.4	102.5	107.7	92.1	98.3	103.3	103.3	95.2	99.9	4.8	4.8	11.5	Pass	99.9	Pass
32	A-113	A113/MM14	OMAC	MDC PHARM	India	93.4	106.4	98.1	93.7	103.5	94.4	91.0	95.3	94.7	105.6	97.6	5.5	5.7	14.2	Pass	97.6	Pass
136	B-012	B-012/MM1	OMAPIN	BRAWN LAB	India	102.2	96.2	110.0	107.4	107.9	108.5	106.8	98.5	103.9	105.3	104.7	4.5	4.3	7.7	Pass	104.7	Pass
140	B-016	B-016/MM1	Sumicef	AMN Life Si	India	106.7	105.7	103.3	107.9	105.9	97.6	104.6	94.6	103.2	104.0	103.4	4.1	4.0	8.1	Pass	103.4	Pass
167	B-043	B-043/MM1	Sumicef	AMN Life Si	India	105.1	104.8	106.7	104.0	108.5	103.9	108.2	107.7	105.3	105.7	106.0	1.7	1.6	9.3	Pass	106.0	Pass
170	B-046	B-046/MM1	OMAC	MDC PHARM	India	109.7	108.2	109.3	100.4	108.1	109.8	106.6	102.4	107.7	107.6	107.0	3.2	2.9	2.1	Pass	107.0	Pass
195	B-071	B-071/MM1	OMAC	MDC PHARM	India	98.0	92.7	99.3	100.4	105.5	90.2	96.2	101.2	101.2	93.3	97.8	4.7	4.8	11.9	Pass	97.8	Pass
198	B-074	B-074/MM1	OMEPRAZOl	GOLDEN KAI	Singapore	88.9	63.0	70.3	62.4	86.7	84.7	70.0	70.9	95.3	91.9	78.4	12.3	15.7	49.7	Fail	78.4	Fail
202	B-078	B-078/MM1	OMAC	MDC PHARM	India	97.1	93.1	100.6	106.6	99.6	98.8	93.2	98.1	104.6	93.3	98.5	4.7	4.7	11.2	Pass	98.5	Pass
**Samples B-077 and B-108 are tablet dosage form																						
TOLERANCE/CRITERIA																						

Result of quantity test and content uniformity test [OM] 2nd stage-BP**



Omeprazole Dissolution 1st Stage-BP

					Kanazawa Univ. Dissolution test BP: 1st stage (Acid resistance Stage– No individual value exceeds 10% dissolved)										Kanazawa Univ. Dissolution test BP: Buffer Stage– No unit is less than Q+5% (Q=60%)									
ID	Serial No.	Sample Code	Trade name of th	Name of Manufa	Manufacti	% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	Disso Final Judge
2	PA-005	PA005/MM14/YK	OMEZ	Dr.REDDY'S LAB	India	26.9	9.3	15.9	26.6	9.3	15.7	17.3	7.9	45.6	Fail	60.1	65.2	61.7	60.1	65.1	61.7	62.3	2.3	3.7	Fail	Fail
3	PA-006	PA006/MM14/YK	OCID	Cadila Healthca	India	5.4	4.0	7.2	4.4	7.2	5.5	5.6	1.4	24.2	Pass	83.1	84.9	82.2	82.7	83.6	82.1	83.1	1.0	1.2	Pass	pass
4	A-001	A001/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	9.8	5.9	7.5	9.3	6.9	7.4	7.8	1.5	19.1	Pass	73.8	79.3	71.4	72.4	71.1	70.8	73.1	3.9	5.4	Pass	pass
5	A-002	A002/MM14/YG	OCID	Cadila Healthca	India	3.0	2.7	2.6	2.6	2.5	4.0	2.9	0.6	19.1	Pass	96.9	99.5	98.2	96.1	96.4	98.4	97.6	1.3	1.4	Pass	pass
6	A-011	A011/MM14/YG	Omesec	The United Drug	Thailand	2.7	2.6	3.1	2.7	2.9	3.0	2.8	0.2	7.0	Pass	93.5	91.0	92.9	89.3	92.8	94.3	92.3	1.8	2.0	Pass	pass
7	A-012	A012/MM14/YG	Zosec	Emcure PHARMA	India	7.2	5.7	5.0	7.1	5.8	5.0	6.0	1.0	16.2	Pass	80.0	74.7	91.1	80.0	76.4	90.3	82.1	7.0	8.5	Pass	pass
8	A-015	A015/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	14.3	9.3	16.8	15.2	15.9	9.7	13.5	3.2	23.9	Fail	56.6	70.7	55.2	54.5	48.1	74.7	60.0	10.4	17.3	Fail	Fail
9	A-026	A026/MM14/YG	OCID	Cadila Healthca	India	9.6	3.6	3.6	3.9	5.8	4.1	5.1	2.3	46.0	Pass	86.9	72.9	75.2	76.9	75.4	86.8	79.0	6.2	7.9	Pass	Pass
10	A-033	A033/MM14/YG	OMPIL20	Pourris Laborato	India	8.3	8.4	8.3	8.6	8.9	8.7	8.5	0.3	3.0	Pass	67.6	81.2	79.8	80.6	68.5	68.2	74.3	6.8	9.2	Fail	Fail
11	A-034	A034/MM14/YG	LOMAC-20	Cipla Ltd.	India	26.9	27.7	27.7	27.3	28.1	23.5	26.9	1.7	6.3	Fail	52.1	53.8	47.6	51.8	50.9	48.5	50.8	2.3	4.6	Fail	Fail
12	A-038	A038/MM14/YG	LOMAC-20	Cipla Ltd.	India	12.5	11.6	12.6	13.0	14.1	15.1	13.1	1.2	9.5	Fail	85.4	84.1	83.3	81.7	85.2	83.6	83.9	1.3	1.6	Pass	Fail
13	A-039	A039/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	9.5	8.5	14.7	14.6	13.1	14.5	12.5	2.8	22.1	Fail	73.9	77.7	62.1	75.0	60.7	60.8	68.4	8.0	11.6	Fail	Fail
14	A-039	A039/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	9.5	8.5	14.7	14.6	13.1	14.5	12.5	2.8	22.1	Fail	73.9	77.7	62.1	75.0	60.7	60.8	68.4	8.0	11.6	Fail	Fail
15	A-041	A041/MM14/YG	TRISEC	GREATHIMALAY	India	12.0	23.0	11.5	11.8	24.9	11.6	16.1	6.8	42.4	Fail	59.7	98.8	61.0	59.7	98.7	61.4	73.2	19.8	27.1	Fail	Fail
16	A-042	A042/MM14/YG	OCID	Cadila Healthca	India	5.6	5.0	3.6	3.8	5.0	5.4	4.7	0.8	17.2	Pass	97.9	95.6	97.7	95.1	96.2	95.7	96.4	1.2	1.2	Pass	Pass
17	A-050	A050/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	10.5	9.2	20.2	17.3	17.9	24.3	16.6	5.8	34.9	Fail	75.3	75.8	60.7	73.7	63.2	74.1	70.5	6.7	9.5	Fail	Fail
18	A-060	A060/MM14/YG	OCID	Cadila Healthca	India	2.4	2.5	4.4	2.9	2.9	2.6	2.9	0.7	24.9	Pass	99.3	98.1	98.6	95.4	99.0	98.0	98.1	1.4	1.4	Pass	Pass
19	A-061	A061/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	9.9	9.5	8.5	9.1	9.9	9.9	9.6	0.3	3.5	Pass	76.8	68.0	70.6	76.9	71.1	76.5	73.3	3.9	5.3	Fail	Fail
20	A-065	A065/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	9.2	9.2	9.1	9.8	7.0	7.4	8.6	1.1	13.3	Pass	72.5	72.1	67.3	67.6	73.4	72.5	70.9	2.7	3.8	Fail	Fail
22	A-067	A067/MM14/YG	HYCID	XL LABORATORIE	India	3.3	9.0	9.0	8.0	5.1	9.1	7.3	2.5	33.8	Pass	82.2	71.8	73.5	86.2	70.2	76.3	76.7	6.3	8.2	Pass	Pass
23	A-076	A076/MM14/YG	ASMOZOL-20	ASMOCH LABORA	India	1.4	1.4	1.4	1.4	1.4	1.4	1.4	0.0	0.0	Pass	82.7	94.3	95.4	96.0	95.4	96.1	93.3	5.2	5.6	Pass	Pass
24	A-078	A078/MM14/YG	Reloc-20	Rhydburg Pharm	India	23.0	34.4	17.1	23.3	33.1	16.6	24.6	7.6	31.1	Fail	49.4	43.5	50.8	49.9	44.1	50.9	48.1	3.4	7.1	Fail	Fail
25	A-084	A084/MM14/YG	OCID	Cadila Healthca	India	9.9	9.5	7.3	9.6	9.7	10.0	9.3	1.0	10.8	Pass	77.0	79.8	80.1	94.3	94.4	95.4	86.8	8.7	10.0	Pass	Pass
26	A-091	A091/MM14/YG	Omesec	The United Drug	Thailand	2.7	3.2	4.7	4.7	2.8	3.3	3.6	0.9	24.7	Pass	89.9	93.5	95.8	99.9	95.9	98.2	95.5	3.5	3.7	Pass	Pass
27	A-096	A096/MM14/YG	Omep-20	ABISTOPHARMA	Banglade	22.3	10.4	8.9	11.6	9.6	10.2	12.2	5.0	41.4	Fail	51.3	79.2	76.0	65.2	77.9	70.0	70.0	10.5	15.1	Fail	Fail
28	A-097	A097/MM14/YG	Omesafe	UNIVERSAL PHAR	India	2.8	2.7	6.7	2.6	2.7	3.6	3.5	1.6	46.1	Pass	94.6	95.2	78.9	96.5	80.6	82.9	88.1	8.1	9.2	Pass	Pass
29	A-101	A101/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	8.9	12.5	9.4	14.3	11.1	14.1	11.7	2.3	19.8	Fail	77.6	69.5	77.7	55.7	66.9	53.7	66.9	10.4	15.5	Fail	Fail
30	A-106	A106/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	1.9	1.9	1.9	1.9	1.9	1.9	1.9	0.0	0.0	Pass	69.0	73.1	66.6	71.7	67.5	72.5	70.1	2.8	3.9	Fail	Fail
31	A-107	A107/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	4.8	4.7	4.6	4.5	4.6	4.4	4.6	0.1	3.3	Pass	18.3	19.5	17.9	18.5	18.9	18.3	18.6	0.6	3.0	Fail	Fail
33	A-114	A114/MM14/YG	OMEZ	Dr.REDDY'S LAB	India	1.9	1.9	1.9	1.9	1.9	1.9	1.9	0.0	0.0	Pass	69.4	67.9	75.2	67.4	67.6	72.5	70.0	3.2	4.5	Fail	Fail
123	PB-002	PB-002/MM14/Y	Ome-M	Rainbow Life Sci	India	11.0	18.1	11.0	17.7	18.2	11.2	14.5	3.8	26.1	Fail	51.5	60.6	59.9	50.7	51.3	60.4	55.7	5.0	9.0	Fail	Fail
124	PB-003	PB-003/MM14/Y	OMEZ	Dr. REDDY'S LAB	India	9.0	8.9	8.9	5.7	3.4	5.1	6.8	2.4	35.4	Pass	30.7	34.4	26.5	54.9	71.2	57.6	45.9	17.9	39.0	Fail	Fail
129	B-005	B-005/MM14/YC	OCID	Cadila Health U	India	6.0	3.6	3.6	3.9	5.8	4.1	4.5	1.1	24.6	Pass	96.0	92.6	95.2	91.6	94.0	95.8	94.2	1.8	1.9	Pass	Pass
130	B-006	B-006/MM14/YC	OMEZ	Dr. REDDY'S LAB	India	5.8	2.9	5.3	9.1	8.8	8.7	6.8	2.5	37.1	Pass	54.7	72.7	57.1	31.1	34.2	27.9	46.3	17.9	38.7	Fail	Fail
131	B-007	B-007/MM14/YC	LOMAC	Cipla Ltd.	India	39.9	38.1	42.5	40.3	39.5	42.3	40.4	1.7	4.2	Fail	49.5	49.7	63.4	55.7	50.7	50.7	53.3	5.5	10.2	Fail	Fail
132	B-008	B-008/MM14/YC	OMEZ	Dr. REDDY'S LAB	India	14.4	13.3	14.5	14.4	8.4	11.0	12.7	2.5	19.6	Fail	70.3	67.7	73.1	72.3	77.4	74.8	72.6	3.4	4.7	Fail	Fail
135	B-011	B-011/MM14/YC	OCID	Cadila Health U	India	5.3	4.0	7.2	4.4	7.2	5.4	5.6	1.4	24.2	Pass	96.6	97.9	98.3	66.4	98.5	97.3	92.5	12.8	13.9	Pass	Pass
137	B-013	B-013/MM14/YC	OMEZ	Dr. REDDY'S LAB	India	16.5	15.8	8.5	15.0	10.6	15.9	13.7	3.4	24.4	Fail	50.2	47.5	80.7	58.6	68.2	56.9	60.4	12.3	20.4	Fail	Fail
139	B-015	B-015/MM14/YC	HYCID	XL LABORATORIE	India	17.9	17.2	17.7	18.0	17.5	17.7	17.7	0.3	1.7	Fail	39.7	38.5	42.8	39.8	38.9	42.6	40.4	1.9	4.6	Fail	Fail
141	B-017	B-017/MM14/YC	Zosec	Emcure PHARMA	India	2.6	2.4	1.8	1.3	1.2	1.0	1.7	0.6	37.4	Pass	99.6	98.6	98.8	97.7	97.4	94.6	97.8	1.8	1.8	Pass	Pass
160	B-036	B-036/MM14/YC	OMEZ	Dr. REDDY'S LAB	India	8.8	7.6	1.0	1.2	0.9	8.0	4.6	3.9	85.4	Pass	78.3	70.7	78.4	69.3	68.3	66.6	71.9	5.1	7.1	Fail	Fail
161	B-037	B-037/MM14/YC	OMPIL	Pourris Laborato	India	3.5	7.1	5.1	4.2	6.8	5.0	5.3	1.4	26.7	Pass	92.2	86.9	87.1	91.1	88.9	92.9	89.9	2.6	2.9	Pass	Pass
169	B-045	B-045/MM14/YC	OMPREZ	Global Pharma H	India	2.6	3.0	4.4	2.5	2.8	4.4	3.3	0.9	26.6	Pass	71.7	94.3	86.6	73.1	93.9	86.8	84.4	9.9	11.7	Pass	Pass
173	B-049	B-049/MM14/YC	Vfrom	Virchow Healthc	India	2.3	2.5	2.7	0.9	0.9	0.9	1.7	0.9	54.1	Pass	66.4	85.3	84.9	65.6	83.7	66.3	75.4	10.2	13.5	Fail	Fail
178	B-054	B-054/MM14/YC	OMEZ	Dr. REDDY'S LAB	India	22.8	26.4	28.2	24.0	25.3	27.4	25.7	2.1	8.0	Fail	31.4	32.1	35.5	31.8	75.9	73.2	46.3	21.2	45.7	Fail	Fail
183	B-059	B-059/MM14/YC	Omesec	The United Drug	Thailand	2.3	2.2	2.7	2.3	2.5	2.6	2.4	0.2	8.2	Pass	93.9	97.7	99.8	93.3	93.4	91.2	94.9	3.2	3.4	Pass	Pass
189	B-065	B-065/MM14/YC	Omep	ABISTOPHARMA	Banglade	11.1	11.3	10.9	11.0	11.2	10.9	11.1	0.2	1.7	Fail	56.0	52.7	47.6	56.4	54.1	48.6	52.6	3.7	7.1	Fail	Fail
194	B-070	B-070/MM14/YC	OCID	Cadila Health U	India	3.7	3.9	3.8	2.5	3.1	2.5	3.3	0.6	19.7	Pass	82.7	94.3	93.5	94.2	95.4	95.7	92.7	4.9	5.3	Pass	Pass
201	B-077	B-077/MM14/YC	Ometab	Intas Pharmaceu	India	1.4	1.4	1.4	1.4	1.4	1.4	1.4	0.0	0.0	Pass	87.1	86.9	87.2	86.4	88.0	87.9	87.2	0.6	0.7	Pass	Pass
213	B-090	B-090/MM14/YC	OCID	Cadila Health U	India	2.2	1.9	1.9	2.0	2.0	2.0	2.0	0.1	6.4	Pass	77.0	79.8	80.1	81.4	80.1	77.2	79.3	1.8	2.2	Pass	Pass
215	B-092	B-092/MM14/YC	OMEPREN	BLUE CROSS LAB	India	2.5	2.4	1.8	1.1	1.2	1.2	1.7	0.6	36.5	Pass	92.8	95.2	98.8	97.5	97.3	94.7	96.0	2.2	2.3	Pass	Pass
221	B-098	B-098/MM14/YC	OMEPREN	BLUE CROSS LAB	India	2.4	2.3	2.5	2.4	2.2	2.4	2.3	0.1	4.6	Pass	81.6	92.7	89.7	83.0	93.3	91.8	88.7	5.1	5.8	Pass	Pass
229	B-106	B106/MM14/YG	OMEZ	Dr. REDDY'S LAB	India	12.4	7.6	14.8	20.7	19.3	20.7	15.9	5.3	33.1	Fail	48.7	47.1	79.3	48.8	77.9	77.0	63.3	16.2	25.6	Fail	Fail
231	B-108	B108/MM14/YG	Ometab	Intas Pharmaceu	India	3.5	7.2	4.9	4.2	6.9	4.9	5.3	1.5	28.3	Pass	92.2	87.5	87.3	91.2	88.4	92.3	89.8	2.3	2.6	Pass	Pass
233	B-110	B110/MM14/YG	LOMAC	Cipla Ltd.	India	24.4	25.4	25.1	24.7	25.4	21.1	24.4	1.7	6.8	Fail	53.6	62.8	62.1	52.8	53.4	62.6	57.9	5.1	8.8	Fail	Fail

Omeprazole Dissolution 1st Stage-USP

						Kanazawa Univ. Dissolution test USP: 1st stage (Acid resistance Stage- No individual value exceeds 15% dissolved)										Kanazawa Univ. Dissolution test USP: Buffer Stage- No unit is less than Q+5% (Q=75%)										
1	PA-004	PA004/MM14/YC	OMAC	MDC PHARMACEI	India	12.6	11.2	12.6	12.8	13.2	11.4	12.3	0.8	6.7	Pass	89.4	90.4	99.5	91.6	92.2	96.4	93.2	3.9	4.2	Pass	Pass
9	A-021	A021/MM14/YG	OMAPIN-20	BRAWN LABORA	India	2.0	4.6	3.7	0.5	2.9	4.5	3.0	1.6	52.7	Pass	86.1	95.4	95.7	96.3	88.0	93.2	92.4	4.3	4.7	Pass	Pass
21	A-066	A066/MM14/YG	OMAC	MDC PHARMACEI	India	11.7	5.3	1.8	12.2	11.3	9.8	8.7	4.2	48.5	Pass	88.8	89.9	98.9	91.0	91.7	95.9	92.7	3.9	4.2	Pass	Pass
32	A-113	A113/MM14/YG	OMAC	MDC PHARMACEI	India	17.1	11.2	7.8	17.6	16.7	15.3	14.3	3.9	27.6	Fail	81.2	77.6	80.0	78.6	77.3	75.9	78.4	1.9	2.5	Fail	Fail
136	B-012	B-012/MM14/YC	OMAPIN	BRAWN LABORA	India	4.3	8.4	6.1	9.8	7.9	8.0	7.4	2.0	26.3	Pass	92.8	97.9	93.9	90.9	92.7	97.6	94.3	2.9	3.0	Pass	Pass
140	B-016	B-016/MM14/YC	Sumicef	AMN Life Sience	India	10.9	10.8	4.0	2.8	8.9	6.9	7.4	3.5	46.8	Pass	89.4	87.9	90.5	92.6	92.2	89.5	90.3	1.8	2.0	Pass	Pass
167	B-043	B-043/MM14/YC	Sumicef	AMN Life Sience	India	5.8	8.3	4.0	1.6	14.0	4.4	6.3	4.3	68.4	Pass	90.7	85.0	90.3	89.7	90.1	91.9	89.6	2.4	2.7	Pass	Pass
170	B-046	B-046/MM14/YC	OMAC	MDC PHARMACEI	India	0.8	1.8	1.6	5.8	4.5	6.9	3.6	2.5	70.0	Pass	83.4	89.1	86.9	88.0	85.5	88.4	86.9	2.1	2.5	Pass	Pass
195	B-071	B-071/MM14/YC	OMAC	MDC PHARMACEI	India	0.6	12.5	6.3	10.1	4.8	2.2	6.1	4.6	75.1	Pass	88.4	89.2	86.4	87.5	93.3	87.8	88.8	2.4	2.7	Pass	Pass
198	B-074	B-074/MM14/YC	OMEPRAZOLE	GOLDEN KABAW	Singapor	14.3	11.3	14.3	10.7	14.1	14.4	13.2	1.7	12.9	Pass	77.1	81.7	80.0	78.6	81.4	77.7	79.4	1.9	2.4	Fail	Fail
202	B-078	B-078/MM14/YC	OMAC	MDC PHARMACEI	India	1.2	1.3	3.4	2.7	1.4	13.5	3.9	4.8	122.3	Pass	85.6	89.2	86.5	87.5	90.0	87.6	87.7	1.6	1.9	Pass	Pass

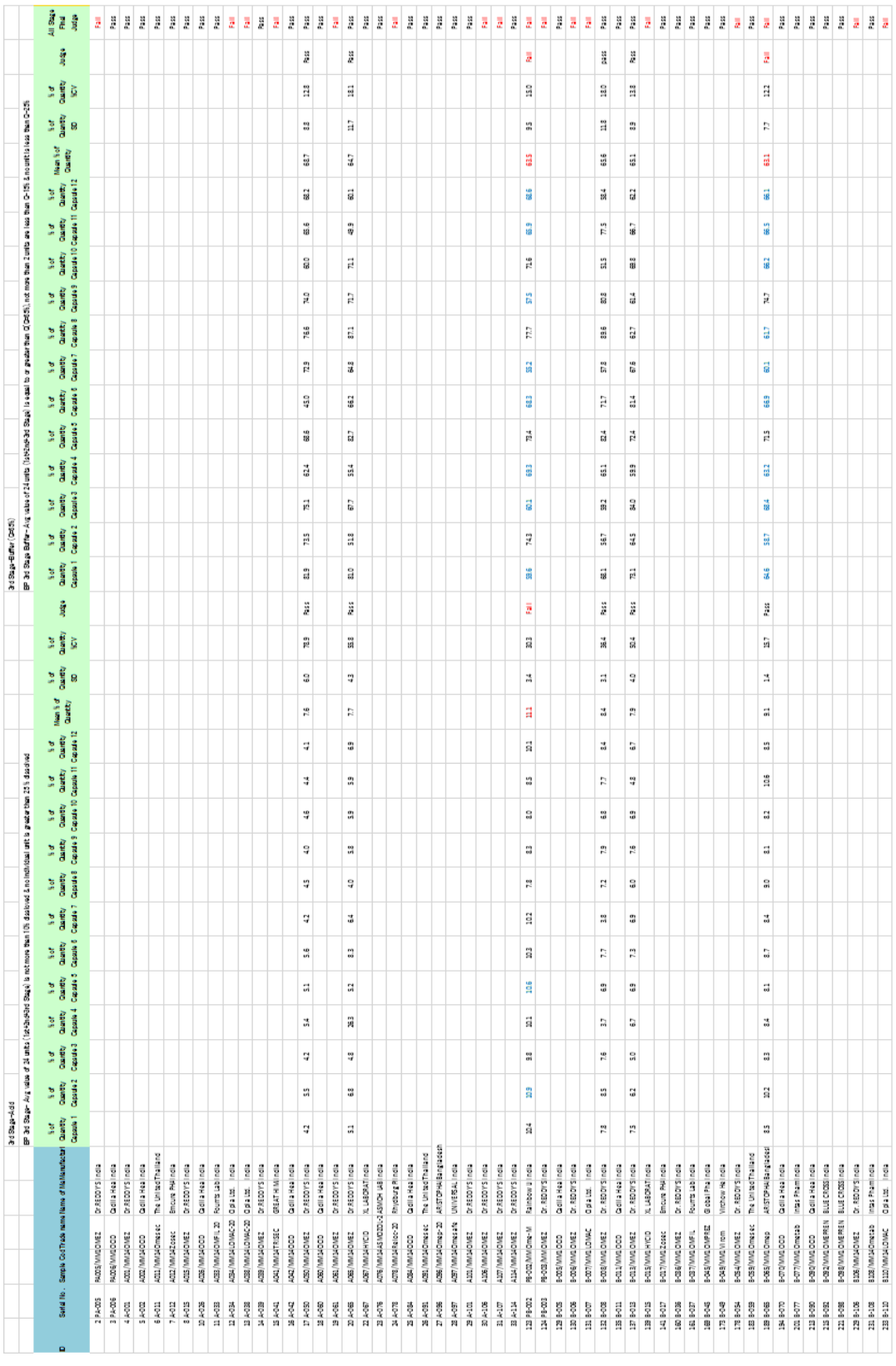
Omeprazole Dissolution 2nd Stage-BP

						2nd Stage-Acid Stage										2nd Stage-Buffer (Q=65%)										
						BP: Acid Stage-Avg value of 12 unit (1st stage+2nd Stage) is not more than 10% dissolved & no individual unit is greater										BP: 2nd stage: Buffer Stage- Avg value of 12 unt (1st+2nd Stage) is equal to or greater than Q (Q=65%) & no unit is less than Q-15%										
ID	Serial No .	Sample Cod	Trade name	Name of Ma	Manufacturi	% of Quantity Capsule 1	% of Quantity capsule 2	% of Quantity Capsule 3	% of Quantity capsule 4	% of Quantity Capsule 5	% of Quantity capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	Disso Final Judge
2	PA-005	PA005/MM1	OMEZ	Dr.REDDY'S	India																					
3	PA-006	PA006/MM1	OCID	Cadila Hea	India																					
4	A-001	A001/MM14	OMEZ	Dr.REDDY'S	India																					
5	A-002	A002/MM14	OCID	Cadila Hea	India																					
6	A-011	A011/MM14	Omesec	The United	Thailand																					
7	A-012	A012/MM14	Zosec	Emcure PHA	India																					
8	A-015	A015/MM14	OMEZ	Dr.REDDY'S	India	4.4	3.9	4.0	5.7	18.3	6.8	10.4	5.4	52.6	Pass	58.8	81.4	72.6	67.6	73.9	64.5	64.9	10.2	15.7	Pass	Pass
10	A-026	A026/MM14	OCID	Cadila Hea	India																					
11	A-033	A033/MM14	OMFIL 20	Fourrts Lab	India	8.0	6.5	6.0	8.6	6.3	7.8	7.9	1.0	13.0	Pass	61.7	78.7	77.4	71.1	81.4	81.0	74.8	6.9	9.2	Pass	Pass
12	A-034	A034/MM14	LOMAC-20	Cipla Ltd.	India																					
13	A-038	A038/MM14	LOMAC-20	Cipla Ltd.	India	33.7	31.6	34.5	34.8	35.5	39.3	24.0	11.5	47.9	Fail	37.1	49.6	41.5	37.8	49.6	40.3	63.2	21.9	34.6	Fail	Fail
14	A-039	A039/MM14	OMEZ	Dr.REDDY'S	India	1.3	5.6	6.8	4.1	4.5	3.8	8.4	4.8	57.0	Pass	80.5	74.6	75.1	60.4	64.0	67.9	69.4	7.5	10.8	Pass	Pass
15	A-041	A041/MM14	TRISEC	GREAT HIM	India	15.6	11.1	11.7	13.1	11.7	12.7	14.4	5.1	35.2	Fail	24.3	18.1	29.6	19.4	22.9	18.6	47.7	30.0	62.9	Fail	Fail
16	A-042	A042/MM14	OCID	Cadila Hea	India																					
17	A-050	A050/MM14	OMEZ	Dr.REDDY'S	India	3.7	4.3	6.6	3.8	3.3	5.1	10.5	7.5	71.0	Fail	67.2	52.1	62.3	79.2	65.7	76.5	68.8	8.2	12.0	Pass	Fail
18	A-060	A060/MM14	OCID	Cadila Hea	India																					
19	A-061	A061/MM14	OMEZ	Dr.REDDY'S	India	8.5	5.7	6.1	7.8	7.0	4.9	8.1	1.8	22.2	Pass	38.4	71.2	56.3	41.9	38.2	69.0	62.9	15.2	24.1	Fail	Fail
20	A-065	A065/MM14	OMEZ	Dr.REDDY'S	India	6.7	8.1	6.6	8.8	4.1	6.9	7.7	1.6	20.8	Pass	60.6	41.1	48.6	52.5	64.5	50.4	61.9	11.1	18.0	Fail	Fail
22	A-067	A067/MM14	HYCID	XL LABORAT	India																					
23	A-076	A076/MM14	ASMOZOL-2	ASMOH LAB	India																					
24	A-078	A078/MM14	Reloc-20	Rhydburg P	India																					
25	A-084	A084/MM14	OCID	Cadila Hea	India																					
26	A-091	A091/MM14	Omesec	The United	Thailand																					
27	A-096	A096/MM14	Omep-20	ARISTOPHA	Banglades	10.2	8.7	3.0	8.9	8.7	10.5	10.3	4.4	42.4	Pass	63.5	71.2	102.5	64.7	76.4	46.9	70.4	14.3	20.3	Pass	Pass
28	A-097	A097/MM14	Omesafe	UNIVERSAL	India																					
29	A-101	A101/MM14	OMEZ	Dr.REDDY'S	India	5.5	7.9	6.2	7.8	7.1	7.4	9.4	3.0	32.1	Pass	69.8	61.6	66.0	53.7	60.9	68.5	65.1	8.3	12.7	Pass	Pass
30	A-106	A106/MM14	OMEZ	Dr.REDDY'S	India	8.0	5.9	6.8	5.0	6.1	8.8	4.3	2.7	62.5	Pass	39.2	67.8	56.7	43.5	41.6	69.6	61.6	12.9	20.9	Fail	Fail
31	A-107	A107/MM14	OMEZ	Dr.REDDY'S	India																					
33	A-114	A114/MM14	OMEZ	Dr.REDDY'S	India	7.2	7.9	5.5	6.4	7.2	8.1	4.5	2.8	61.8	Pass	53.0	69.8	66.7	60.4	61.1	66.8	66.5	5.9	8.9	Pass	Pass
123	PB-002	PB-002/MM	Ome-M	Rainbow Li	India	11.6	3.0	13.5	12.7	11.0	12.3	12.6	4.2	33.0	Fail	61.8	90.6	60.5	64.9	57.5	53.4	60.2	10.7	17.7	Fail	Fail
124	PB-003	PB-003/MM	OMEZ	Dr. REDDY'S	India																					
129	B-005	B-005/MM1	OCID	Cadila Hea	India																					
130	B-006	B-006/MM1	OMEZ	Dr. REDDY'S	India																					
131	B-007	B-007/MM1	LOMAC	Cipla Ltd.	India																					
132	B-008	B-008/MM1	OMEZ	Dr. REDDY'S	India	7.0	6.5	8.8	4.3	6.9	8.4	9.8	3.6	36.4	Pass	63.3	52.7	60.6	51.7	42.5	50.0	63.0	11.4	18.2	Fail	Fail
135	B-011	B-011/MM1	OCID	Cadila Hea	India																					
137	B-013	B-013/MM1	OMEZ	Dr. REDDY'S	India	3.8	6.8	3.9	5.1	3.6	4.6	9.2	5.3	58.0	Pass	65.6	54.7	62.1	63.1	63.3	64.9	61.3	8.8	14.3	Fail	Fail
139	B-015	B-015/MM1	HYCID	XL LABORAT	India																					
141	B-017	B-017/MM1	Zosec	Emcure PHA	India																					
160	B-036	B-036/MM1	OMEZ	Dr. REDDY'S	India	8.8	10.7	9.1	10.0	8.2	12.8	7.3	4.0	55.2	Pass	74.9	64.9	61.2	65.5	62.3	75.3	69.6	5.9	8.5	Pass	Pass
161	B-037	B-037/MM1	OMFIL	Fourrts Lab	India																					
169	B-045	B-045/MM1	OMPREZ	Global Pha	India																					
173	B-049	B-049/MM1	Virom	Virchow He	India	8.0	7.5	6.8	6.7	6.4	7.8	4.4	3.0	67.2	Pass	65.6	72.1	81.4	78.6	78.2	80.4	75.7	8.0	10.5	Pass	Pass
178	B-054	B-054/MM1	OMEZ	Dr. REDDY'S	India																					
183	B-059	B-059/MM1	Omesec	The United	Thailand																					
189	B-065	B-065/MM1	Omep	ARISTOPHA	Banglades	7.8	8.3	6.8	7.7	6.8	9.5	9.4	1.8	19.4	Pass	71.2	64.9	74.5	64.9	73.3	61.8	60.5	9.4	15.5	Fail	Fail
194	B-070	B-070/MM1	OCID	Cadila Hea	India																					
201	B-077	B-077/MM1	Ometab	Intas Pharn	India																					
213	B-090	B-090/MM1	OCID	Cadila Hea	India																					
215	B-092	B-092/MM1	OMEPREN	BLUE CROSS	India																					
221	B-098	B-098/MM1	OMEPREN	BLUE CROSS	India																					
229	B-106	B106/MM14	OMEZ	Dr. REDDY'S	India	12.0	16.3	11.1	12.1	14.2	11.2	14.4	4.1	28.8	Fail	34.0	27.7	31.1	32.4	28.6	26.2	46.6	20.7	44.3	Fail	Fail
231	B-108	B108/MM14	Ometab	Intas Pharn	India																					
233	B-110	B110/MM14	LOMAC	Cipla Ltd.	India	25.0	25.8	22.1	26.5	27.9	32.4	25.5	2.8	11.1	Fail	35.2	34.1	32.5	34.1	35.7	37.1	46.3	12.6	27.2	Fail	Fail

Omeprazole Dissolution 2nd Stage-USP

				2nd Stage-Acid Stage									2nd Stage-Buffer (Q=75%)									
	USP Samples		USP Acid Stage-Avg value of 12 unit (1st stage+2nd Stage) is not more than 20% dissolved & no individual unit is greater																			
1	PH-0004	PH0004/WM/LOMAC	MDC PHARM India																			
9	A-0021	A0021/WM/LOMAPRN-20	BRAWN LAB India																			
21	A-0665	A0665/WM/LOMAC	MDC PHARM India																			
32	A-113	A113/WM/LOMAC	MDC PHARM India	7.7	2.2	0.3	3.1	0.3	5.2	8.7	6.7	79.8	Pass	100.8	102.5	109.9	116.5	101.8	105.6	92.3	15.1	16.4	Pass	Pass
136	B-012	B-012/WM/LOMAPRN	BRAWN LAB India																					
140	B-016	B-016/WM/Sumicef	AWM Life Sl India																					
167	B-043	B-043/WM/Sumicef	AWM Life Sl India																					
170	B-046	B-046/WM/LOMAC	MDC PHARM India																					
195	B-071	B-071/WM/LOMAC	MDC PHARM India																					
198	B-074	B-074/WM/LOMEPRAZOLEGOLDEN	KA Singapore	2.6	2.9	1.9	1.8	0.7	0.6	7.5	6.1	81.7	Pass	90.6	103.7	94.0	96.5	100.9	85.1	87.3	9.5	10.9	Pass	Pass
202	B-078	B-078/WM/LOMAC	MDC PHARM India																					

Omeprazole Dissolution 3rdStage-BP



Result of Sterility and Endotoxin test (CTRX)

ID	Serial No.	Sample Code	tch/Lot num	Trade name of the product	Name of Manufacture	Manufacturing Country	Sterility test soybean	Sterility test thioglycollat	Endotoxin test
1	A-031	A031/MM14/YG/01	189	PARCEF	Jayson Pha	Bangladest	pass	pass	pass
2	A-087	A087/MM14/YG/01	303004	Ceftron	SQUARE PI	Bangladest	pass	pass	pass
3	A-093	A093/MM14/YG/03	131001	DALITRIXON	SHENZHEN	China	pass	pass	pass
7	A-046	A046/MM14/YG/05	LHA13038	C-Tri 1.0g	Emcure PH	India	pass	pass	pass
10	A-013	A013/MM14/YG/01	AL234E	LYFAXONE	LYKA LABS	India	pass	pass	pass
11	A-029	A029/MM14/YG/04	AL235E	LYFAXONE	LYKA LABS	India	pass	pass	pass
12	A-062	A062/MM14/YG/01	AL277E	LYFAXONE	LYKA LABS	India	pass	pass	pass
13	A-081	A081/MM14/YG/02	AL223E	LYFAXONE	LYKA LABS	India	pass	pass	pass
15	A-009	A009/MM14/YG/01	T3C100114	CEFTRIAXONE	M.J.BIOPH.	India	pass	pass	pass
16	A-098	A098/MM14/YG/01	T3C100114	CEFTRIAXONE	M.J.BIOPH.	India	pass	pass	pass
17	A-010	A010/MM14/YG/01	GBIC14010	BECEF	Nectar Life	India	pass	pass	pass
18	A-027	A027/MM14/YG/04	GBIC13017	BECEF	Nectar Life	India	pass	pass	pass
19	A-056	A056/MM14/YG/01	GBIC14012	BECEF	Nectar Life	India	pass	pass	pass
20	A-103	A103/MM14/YG/02	CRIC14015	BECEF	Nectar Life	India	pass	pass	pass
21	A-109	A109/MM14/YG/01	6B1C14015	BECEF	Nectar Life	India	pass	pass	pass
31	PA-007	PA007/MM14/YG/0	2445124	Oframax	RANBAXY L	India	pass	pass	pass
32	A-008	A008/MM14/YG/01	2520523	Oframax	RANBAXY L	India	pass	pass	pass
33	A-051	A051/MM14/YG/01	2465924	Oframax	RANBAXY L	India	pass	pass	pass
34	A-055	A055/MM14/YG/01	2511401	Oframax	RANBAXY L	India	pass	pass	pass
35	A-082	A082/MM14/YG/02	2465924	Oframax	RANBAXY L	India	pass	pass	pass
36	A-028	A028/MM14/YG/04	STI1315002	TEFAXONE	Stallion LA	India	pass	pass	pass
38	A-032	A032/MM14/YG/03	V34034	UTRIXONE-10	UMEDICA L	India	pass	pass	pass
39	A-073	A073/MM14/YG/01	121127	UTRIXONE-10	UMEDICA L	India	pass	pass	pass
42	A-047	A047/MM14/YG/05	130931	TRAXONE	Korea Phar	Korea	pass	pass	pass
46	A-045	A045/MM14/YG/04	9173G0	CEFTRIAXONE	Myanmar I	Myanmar	pass	pass	pass
47	A-094	A094/MM14/YG/03	GN38	TRAXEF	CCL Pharm	Pakistan	pass	pass	pass
49	A-110	A110/MM14/YG/01	PB356M	Trixone	TOQURE PI	Unknown	pass	pass	pass
134	B-010	B-010/MM14/YG/0:	C400052	Cefaxone	LUPIN LTD.	India	pass	pass	pass
138	B-014	B-014/MM14/YG/0:	LHA13011	C-Tri	Emcure PH	India	pass	pass	pass
144	B-020	B-020/MM14/YG/0!	3WE-105	UTRIXONE	UMEDICA L	India	pass	pass	pass
145	B-021	B-021/MM14/YG/0!	BU-017C6	CEFDEC	BELCO PH	India	pass	pass	pass
148	B-024	B-024/MM14/YG/0!	217281	Ceftriaxone Ir	Myanma P	Myanmar	pass	pass	pass
149	B-025	B-025/MM14/YG/0!	2665N1	Ceftriaxone Ir	Myanma P	Myanmar	pass	pass	pass
156	B-032	B-032/MM14/YG/0:	2511401	Oframax	RANBAXY L	India	pass	pass	pass
157	B-033	B-033/MM14/YG/0:	B0132	Rocephin	F.Hoffman	Switzland	pass	pass	pass
163	B-039	B-039/MM14/YG/0:	2511857	Oframax	RANBAXY L	India	pass	pass	pass
165	B-041	B-041/MM14/YG/0:	WM13003	POWERCEF	WOCKHAR	India	pass	pass	pass
179	B-055	B-055/MM14/YG/0:	GBIC13007	BECEF	Nectar Life	India	pass	pass	pass
180	B-056	B-056/MM14/YG/0:	2520523	Oframax	RANBAXY L	India	pass	pass	pass
181	B-057	B-057/MM14/YG/0:	GN1005	ZEFONE	Cadila Heal	India	pass	pass	pass
185	B-061	B-061/MM14/YG/0:	AL224E	LYFAXONE	LYKA LABS	India	pass	pass	pass
186	B-062	B-062/MM14/YG/0:	2465924	Oframax	RANBAXY L	India	pass	pass	pass
197	B-073	B-073/MM14/YG/0:	WM13007	POWERCEF	WOCKHAR	India	pass	pass	pass
206	B-082	B-082/MM14/YG/0:	GN1002	ZEFONE	Cadila Heal	India	pass	pass	pass
207	B-083	B-083/MM14/YG/0:	GBIC14012	BECEF	Nectar Life	India	pass	pass	pass
211	B-087	B-087/MM14/YG/0:	130931	TRAXONE	Korea Phar	Korea	pass	pass	pass
220	B-097	B-097/MM14/YG/0:	GBIC1307	BECEF	Nectar Life	India	pass	pass	pass
226	B-103	B-103/MM14/YG/0:	2518117	Oframax	RANBAXY L	India	pass	pass	pass
235	B-112	B-112/MM14/YG/0!	2520523	Oframax	RANBAXY L	India	pass	pass	pass

Ceftriaxone Inj. Myanmar-2014

Kanazawa Univ. Content uniformity test (1st stage) | tolerance: AV≦15.0 | 90.0≦mean≦115.0

ID	Serial No.	Sample Code	Trade name o	Name of Man	Manufacturing	% of Quantity Vial1	% of Quantity Vial 2	% of Quantity Vial 3	% of Quantity Vial 4	% of Quantity Vial 5	% of Quantity Vial 6	% of Quantity Vial 7	% of Quantity Vial 8	% of Quantity Vial 9	% of Quantity Vial 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	QTY Judge	AV (Acceptance Value)	CU Judge	AV (Acceptance Value)	Final CU Judge	Kanazawa Univ. Quantity test (10 Vials)	Judge
1	A-010	A010/MM14/	BECEF	Nectar Lifesc	India	124.43	122.277	117.405	111.121	122.58	119.109	115.877	111.927	119.555	112.343	117.7	4.763133544	4.048135635	Fail	27.63	Fail	27.63	Fail	117.66	Fail
2	A-028	A028/MM14/	TEFAXONE	Stallion LABC	India	102.6	102.6	103.4	105.3	104.2	104.1	101.2	103.0	103.5	103.0	103.3	1.120403325	1.084710913	Pass	4.49	Pass	4.49	Pass	103.29	Pass
3	A-047	A047/MM14/	TRAXONE	Korea Pharma	Korea	107.8	108.2	109.4	107.9	105.1	108.6	106.3	108.6	109.0	108.6	108.0	1.301357001	1.205288283	Pass	9.62	Pass	9.62	Pass	107.97	Pass
4	A-062	A062/MM14/	LYFAXONE	LYKA LABS L	India	111.0	110.2	112.2	113.9	115.4	111.1	115.0	110.3	111.4	110.3	112.1	1.996457532	1.781220224	Pass	15.00	Pass	15.00	Pass	112.08	Pass
5	A-087	A087/MM14/	Ceftron	SQUARE PH/	Bangladesh	106.5	104.4	106.2	108.2	105.9	109.3	107.5	109.5	105.8	109.5	107.3	1.788274761	1.667065745	Pass	10.10	Pass	10.10	Pass	107.27	Pass
6	A-083	A083/MM14/	DALITRIXON	SHENZHEN Z	China	107.8	108.6	108.8	108.2	110.6	110.6	110.3	105.4	109.5	105.4	108.5	1.920772197	1.770239851	Pass	11.61	Pass	11.61	Pass	108.50	Pass
7	A-084	A084/MM14/	TRAXEF	OCL Pharmac	Pakistan	108.8	108.3	108.7	108.9	108.3	107.7	107.8	108.8	110.9	108.8	108.7	0.879250849	0.809874705	Pass	9.31	Pass	9.31	Pass	108.70	Pass
8	B-014	B-014/MM14	C-Tri	Emcure PHAF	India	108.6	109.9	108.3	109.1	107.7	107.4	109.1	107.7	108.6	107.7	108.4	0.821127741	0.757498615	Pass	8.87	Pass	8.87	Pass	108.40	Pass
9	B-020	B-020/MM14	UTRIXONE	UMEDICA LA	India	106.5	105.2	106.2	103.7	104.6	106.2	109.2	109.8	107.0	109.8	106.8	2.142310528	2.005630801	Pass	10.34	Pass	10.34	Pass	106.81	Pass
10	B-041	B-041/MM14	POWERCEF	WOCKHARDT	India	105.7	106.0	108.9	106.6	103.9	105.9	103.7	107.6	105.2	107.6	106.2	1.869158816	1.759981861	Pass	10.19	Pass	10.19	Pass	106.20	Pass
11	B-082	B-082/MM14	ZEFONE	Cadila Health	India	109.2	108.5	109.4	108.2	108.1	105.6	106.0	107.7	108.5	107.7	108.0	1.298866296	1.202710773	Pass	9.62	Pass	9.62	Pass	107.99	Pass
12	PA-007	PA007/MM14	Oframax	RANBAXY LA	India	108.7	109.0	108.3	108.2	108.5	108.9	107.7	108.0	110.3	108.0	108.5	0.732883506	0.675192991	Pass	8.75	Pass	8.75	Pass	108.54	Pass
13	A-031	A031/MM14/	PARCEF	Jayson Pharm	Bangladesh	88.34	139.89	135.054	124.33	117.37	121.06	107.18	122.06	124.42	121.78	118.6	13.86001273	11.68561787	Fail	50.36	Fail	50.36	Fail	118.61	Fail
14	A-098	A098/MM14/	CEFTRIAX(	M.J.BIOPHAR	India	106.39	113.20	109.84	114.41	112.13	111.64	110.36	108.79	109.40	110.76	110.7	2.303082823	2.080633927	Pass	14.72	Pass	14.72	Pass	110.69	Pass
15	B-021	B-021/MM14	CEFDEC	BELCO PHAF	India	106.65	110.03	111.10	106.70	107.92	108.31	105.68	107.16	105.24	107.51	107.6	1.823169368	1.693940352	Pass	10.46	Pass	10.46	Pass	107.63	Pass
16	B-025	B-025/MM14	Ceftriaxon	Myanma Phar	Myanmar	106.55	105.70	109.19	105.16	104.43	109.46	113.24	113.02	103.04	102.31	107.2	3.875494956	3.614876799	Pass	15.00	Pass	15.00	Pass	107.21	Pass
17	B-033	B-033/MM14	Rocephin	F.Hoffmann-L	Switzland	111.40	109.24	112.44	111.26	110.71	114.94	111.58	115.00	109.41	109.91	111.6	2.043129737	1.830953368	Pass	15.00	Pass	15.00	Pass	111.59	Pass
18	A-055	A055/MM14/	Oframax	RANBAXY LA	India	114.68	103.49	104.38	103.70	104.15	104.08	103.53	105.26	107.14	105.26	105.6	3.388622055	3.209928543	Pass	12.23	Pass	12.23	Pass	105.57	Pass
19	B-097	B-097/MM14	BECEF	Nectar Lifesc	India	113.50	113.38	113.42	114.97	115.92	114.78	115.17	113.23	113.86	113.23	114.1	0.977012163	0.855938768	Pass	14.95	Pass	14.95	Pass	114.15	Pass
20	A-027	A027/MM14/	BECEF	Nectar Lifesc	India	106.35	109.31	104.98	102.93	105.69	108.25	106.14	106.87	104.40	104.51	106.1	2.095874469	1.974600434	Pass	9.64	Pass	9.64	Pass	106.14	Pass
21	A-029	A029/MM14/	LYFAXONE	LYKA LABS L	India	108.98	103.90	107.80	101.91	102.47	109.30	105.43	107.81	105.95	101.11	105.5	3.0044357	2.84872124	Pass	11.10	Pass	11.10	Pass	105.47	Pass
22	A-051	A051/MM14/	Oframax	RANBAXY LA	India	111.91	105.87	104.91	104.09	105.81	105.61	103.08	110.40	107.50	108.68	106.8	2.810425084	2.631863662	Pass	12.53	Pass	12.53	Pass	106.78	Pass
23	A-110	A110/MM14/	Trixone	TOQURE Pha	India	104.25	97.81	101.04	99.92	106.75	101.00	103.82	101.96	105.13	103.37	102.5	2.665173207	2.600064726	Pass	7.41	Pass	7.41	Pass	102.50	Pass
24	B-010	B-010/MM14	Cefaxone	LUPIN LTD.	India	109.63	104.08	103.56	106.66	109.69	104.92	103.62	104.70	106.78	104.55	105.8	2.303550207	2.176877694	Pass	9.82	Pass	9.82	Pass	105.82	Pass
25	A-008	A008/MM14/	Oframax	RANBAXY LA	India	110.31	107.77	108.26	107.07	108.79	107.31	108.13	108.93	107.37	110.81	108.5	1.2628433	1.164260573	Pass	10.02	Pass	10.02	Pass	108.48	Pass
26	A-009	A009/MM14/	CEFTRIAX(	M.J.BIOPHAR	India	105.85	107.98	105.72	108.70	102.81	101.20	104.49	106.38	102.49	104.89	105.1	2.390506455	2.275567539	Pass	9.34	Pass	9.34	Pass	105.05	Pass
27	A-032	A032/MM14/	UTRIXONE	UMEDICA LA	India	108.28	111.14	105.56	108.08	108.21	109.42	105.26	104.61	105.13	103.78	106.9	2.401543774	2.245577209	Pass	11.06	Pass	11.06	Pass	106.95	Pass
28	A-045	A045/MM14/	Ceftriaxon	Myanmar Pha	Myanmar	96.26	96.03	105.16	101.32	101.42	99.78	99.51	105.68	103.21	101.37	101.0	3.255772763	3.224380836	Pass	6.16	Pass	6.16	Pass	100.97	Pass
29	A-046	A046/MM14/	C-Tri	Emcure PHAF	India	110.51	111.25	113.27	114.43	110.83	110.24	113.82	112.08	111.77	109.20	111.7	1.676665676	1.500515643	Pass	14.23	Pass	14.23	Pass	111.74	Pass
30	A-056	A056/MM14/	BECEF	Nectar Lifesc	India	108.18	112.41	108.56	110.26	108.53	110.00	111.65	110.55	110.44	111.12	110.3	1.299849158	1.17879301	Pass	11.92	Pass	11.92	Pass	110.27	Pass
31	A-073	B-073/MM14	POWERCEF	WOCKHARDT	India	107.90	109.01	108.50	111.99	111.01	110.76	110.67	107.57	107.91	108.79	109.5	1.534190416	1.400614651	Pass	11.96	Pass	11.96	Pass	109.52	Pass
32	A-081	A081/MM14/	LYFAXONE	LYKA LABS L	India	106.00	102.23	104.36	109.30	106.48	110.40	108.38	105.97	104.48	105.96	106.4	2.450182714	2.303799306	Pass	10.78	Pass	10.78	Pass	106.35	Pass
33	A-082	A082/MM14/	Oframax	RANBAXY LA	India	103.21	107.15	111.10	106.50	108.35	105.71	103.68	112.17	106.11	111.17	107.5	3.130877302	2.912029545	Pass	12.41	Pass	12.41	Pass	107.52	Pass
34	A-103	A103/MM14/	BECEF	Nectar Lifesc	India	108.10	105.28	110.35	104.52	110.46	105.80	106.02	106.84	106.12	107.00	107.0	2.018169713	1.885313552	Pass	10.34	Pass	10.34	Pass	107.05	Pass
35	A-109	A109/MM14/	BECEF	Nectar Lifesc	India	111.31	113.98	112.48	113.15	112.38	109.38	108.94	109.62	108.23	110.86	111.1	1.853036995	1.667437735	Pass	14.04	Pass	14.04	Pass	111.13	Pass
36	A-013	A013/MM14/	LYFAXONE	LYKA LABS L	India	94.63	102.90	96.61	98.98	97.82	103.60	92.65	96.80	100.11	95.75	98.0	3.482419225	3.554142532	Pass	8.85	Pass	8.85	Pass	97.98	Pass
37	B-024	B-024/MM14	Ceftriaxon	Myanma Phar	Myanmar	102.71	98.63	104.18	103.42	102.42	103.75	105.73	102.97	102.37	112.55	103.9	3.543077444	3.41097745	Pass	10.90	Pass	10.90	Pass	103.87	Pass
38	B-032	B-032/MM14	Oframax	RANBAXY LA	India	110.28	104.87	106.17	106.59	105.97	106.34	108.70	107.96	105.27	107.96	107.0	1.678909646	1.56891901	Pass	9.53	Pass	9.53	Pass	107.01	Pass
39	B-039	B-039/MM14	Oframax	RANBAXY LA	India	106.22	109.23	110.80	106.04	107.99	105.95	106.38	109.92	104.93	105.62	107.3	2.033010797	1.894544242	Pass	10.37	Pass	10.37	Pass	107.31	Pass
40	B-055	B-055/MM14	BECEF	Nectar Lifesc	India	101.25	101.43	100.30	100.81	105.88	99.54	99.47	102.22	102.02	106.88	102.0	2.507430989	2.458720539	Pass	6.52	Pass	6.52	Pass	101.98	Pass
41	B-056	B-056/MM14	Oframax	RANBAXY LA	India	110.41	110.13	111.47	105.49	105.83	107.83	105.51	109.49	106.90	108.44	108.1	2.196730032	2.02197356	Pass	11.14	Pass	11.14	Pass	108.15	Pass
42	B-057	B-057/MM14	ZEFONE	Cadila Health	India	111.36	106.88	107.80	109.84	104.50	108.12	106.75	106.56	108.64	115.63	108.6	3.106838951	2.860562818	Pass	14.55	Pass	14.55	Pass	108.61	Pass
43	B-061	B-061/MM14	LYFAXONE	LYKA LABS L	India	106.00	105.14	105.92	107.70	105.27	107.78	107.32	105.02	105.71	106.73	106.3	1.052542894	0.990543769	Pass	7.76	Pass	7.76	Pass	106.26	Pass
44	B-062	B-062/MM14	Oframax	RANBAXY LA	India	106.32	107.39	108.88	104.83	108.49	108.77	108.36	107.41	103.07	106.87	107.1	1.977760406	1.845993397	Pass	10.25	Pass	10.25	Pass	107.14	Pass
45	B-073	B-073/MM14	POWERCEF	WOCKHARDT	India	101.75	100.85	100.83	100.81	99.60	98.52	96.52	101.97	97.38	99.22	99.7	1.835222692	1.839889019	Pass	5.44	Pass	5.44	Pass	99.75	Pass
46	B-083	B-083/MM14	BECEF	Nectar Lifesc	India	107.99	107.29	104.44	103.85	108.00	105.91	108.69	104.77	105.71	108.60	106.5	1.81218948	1.701196608	Pass	9.35	Pass	9.35	Pass	106.52	Pass
47	B-087	B-087/MM14	TRAXONE	Korea Pharma	Korea	98.19	97.05	98.98	100.26	103.23	99.78	100.37	104.65	102.74	104.84	101.0	2.709104465	2.682033361	Pass	6.50	Pass	6.50	Pass	101.01	Pass
48	B-103	B-103/MM14	Oframax	RANBAXY LA	India	107.53	106.38	108.51	109.16	109.26	109.78	111.26	109.71	110.73	6.75	98.9	32.41287574	32.77095313	Pass	77.79	Fail	77.79	Fail	98.91	Pass
49	B-112	B-112/MM14	Oframax	RANBAXY LA	India	99.98	99.91	105.18	101.63	95.14	103.85	102.05	98.52	102.12	99.73	100.8	2.833519711	2.810722224	Pass	6.80	Pass	6.80	Pass	100.81	Pass
50	#B-103	B-103/MM14	Oframax	RANBAXY LA	India	102.7	108.6	105.1	104.4	102.5	105.8	104.2	108.7	107.0	112.1	106.1	3.0	2.8	Pass	11.8	Pass				

* The Sceond stage was examined by 10 vials because of insufficient amount of doses.

Result of quality test (DN)

				Kanazawa Univ. Content uniformity test (1st stage)														90.0≦mean≦110.0	
ID	Serial No.	Sample Code No.	Trade name of the product	Name of Manufacturer & Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	% of Quantity Tablet 7	% of Quantity Tablet 8	% of Quantity Tablet 9	% of Quantity Tablet 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge	Kanazawa Univ. Quantity test (10 tabs)	Judge
56	A-044/AM4/WM14/	Arixep 5	Eisai Pharm.India		96.90	99.10	99.50	100.90	99.40	99.50	102.30	99.40	101.10	97.00	99.40	1.87	1.90		pass	99.40	pass
99	A-064/092/WM14/	Arixept Evess	Eisai Co.,Lt	Japan	99.00	102.20	101.00	104.20	101.20	101.20	103.20	103.20	103.10	106.60	103.10	2.60	2.70		pass	103.10	pass
217	B-065-094/WM14/	Arixept Evess	Eisai Co., L	Japan	100.50	99.10	99.70	101.80	100.50	95.20	102.20	99.70	101.60	99.90	100.00	2.39	2.40		pass	100.00	pass

Result of dissolution test (DN)

ID	Serial No.	Sample Code No.	Trade name of the product	Name of Manufacturer	Manufacturing Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge
56	A-049	A049/WM14/YG/07/C/AR	Arixep 5	Eisai Pharmatechnolc	India	104.91	102.23	104.09	102.11	89.28	99.50	100.35	5.24		pass
99	A-092	A092/WM14/YG/02/W/AR	Arixept Evess 5 mg	Eisai Co.,Ltd.	Japan	96.52	99.97	97.79	100.30	101.77	100.49	99.47	1.77		pass
217	B-094	B-094/WM14/YG/02/C/AR	Arixept Evess	Eisai Co., Ltd.,	Japan	96.05	99.61	96.42	102.98	99.50	99.10	98.95	2.30		pass

Result of Identification test [GM]

Serial No.	Sample Code	Batch/Lot No.	Trade name of the product	Name of Manufacturer	Manufacturing Country	Identification	Gentamicin C1/RS	Gentamicin C1a/RS	Gentamicin C2a/RS	Gentamicin C2/RS	others	irregular peak
A-069	A069/MM14/YG/02/C/GM	20140628	GENTAMICIN SULFATE	BEVERLY HENAN PHAR	China	fail	0.057	0.07	0.078	0.079	not detected	no
A-014	A014/MM14/YG/01/HG/GM	86GGA001	Gentamicin 80mg	Fresenius Kabi Bidiphar	Vietnam	pass	0.96	2.05	0.13	1.13	not detected	no
A-090	A090/MM14/YG/02/W/GM	86HBA002	Gentamicin 80mg	Fresenius Kabi Bidiphar	Vietnam	pass	1.01	2.07	1.34	1.27	not detected	no
B-064	B-064/MM14/YG/01/O(c)/GM	86HBA001	Gentamicin 80mg	Fresenius Kabi Bidiphar	Vietnam	pass	1.34	2.77	1.79	1.69	not detected	no
A-020	A020/MM14/YG/01/C/GM	20130406	GENTAMYCIN SULFATE	HENAN DEKANG PHAR	China	fail	0	0	0	0	not detected	no
A-077	A077/MM14/YG/02/C/GM	20130406	GENTAMYCIN SULFATE	HENAN DEKANG PHAR	China	fail	0	0	0	0	not detected	no
B-051	B-051/MM14/YG/03/C/GM	MM20140725	GENTAMEDINE	KUNMING PHARMACEU	China	pass	1.2	1.77	1.73	1.5	not detected	no
PA-003	PA003/MM14/YG/01/C/GM	MM20140528	GENTAMEDINE	KUNMING PHARMACEU	China	pass	1.33	1.73	1.5	1.58	not detected	no
B-018	B-018/MM14/YG/04/C/GM	14351904	MERIGENTA	MERCURY Laboratories	India	pass	1.13	2.06	1.5	1.4	not detected	no
B-019	B-019/MM14/YG/05/C/GM	14351902	MERIGENTA	MERCURY Laboratories	India	pass	0.85	1.79	1.09	1.01	not detected	no
B-075	B-075/MM14/YG/01/HG/GM	14351903	MERIGENTA	MERCURY Laboratories	India	pass	0.79	1.65	1.03	0.94	not detected	no
B-022	B-022/MM14/YG/06/C/GM	62040	GENTAMICIN INJECTIO	Myanma Pharmaceutical	Myanmar	pass	0.74	1.71	1.07	0.98	not detected	no
B-068	B-068/MM14/YG/01/C/GM	1179084	GENTAMICIN INJECTIO	Myanma Pharmaceutical	Myanmar	pass	0.65	1.45	0.87	0.89	not detected	no
B-105	B-105/MM14/YG/01/HG/GM	0787M1	GENTAMICIN INJECTIO	Myanma Pharmaceutical	Myanmar	pass	0.29	2.02	0.88	1.42	not detected	no
B-058	B-058/MM14/YG/01/HP/GM	7874C5	GENTAMICIN INJECTIO	No.(1)Pharmaceutical Fa	Myanmar	pass	0.31	1.67	0.68	1.1	not detected	no
B-060	B-060/MM14/YG/01/HP/GM	7272C5	GENTAMICIN INJECTIO	No.(1)Pharmaceutical Fa	Myanmar	pass	0.44	2.65	1.08	1.84	not detected	no
A-004	A004/MM14/YG/04/HG/GM	1874094	GENTAMICIN INJECTIO	No.(2)Pharmaceutical Fa	Myanmar	pass	0.75	1.58	1.01	0.95	not detected	no
A-024	A024/MM14/YG/04/C/GM	8073053	GENTAMICIN INJECTIO	No.(2)Pharmaceutical Fa	Myanmar	pass	0.65	1.43	0.87	0.88	not detected	no
A-044	A044/MM14/YG/04/C/GM	161040	GENTAMICIN INJECTIO	No.(2)Pharmaceutical Fa	Myanmar	pass	0.75	1.57	0.96	0.89	not detected	no
A-111	A111/MM14/YG/01/C/GM	1572084	GENTAMICIN INJECTIO	No.(2)Pharmaceutical Fa	Myanmar	pass	0.75	1.71	1.07	0.97	not detected	no
B-085	B-085/MM14/YG/02/C/GM	160040	GENTAMICIN INJECTIO	No.(2)Pharmaceutical Fa	Myanmar	pass	0.63	1.35	0.83	0.77	not detected	no
B-107	B-107/MM14/YG/02/HG/GM	162040	GENTAMICIN INJECTIO	No.(2)Pharmaceutical Fa	Myanmar	pass	0.77	1.67	1.04	0.98	not detected	no
B-069	B-069/MM14/YG/01/C/GM	612010	GENTAMICIN	PHARBACO CENTRAL F	Vietnam	pass	1.16	1.55	1.43	1.4	not detected	no
B-072	B-072/MM14/YG/01/HG/GM	RG321	REGENTA	Regain Laboratories	India	pass	0.92	1.7	1.24	1.18	not detected	no
B-109	B-109/MM14/YG/01/C/GM	RG314	REGENTA	Regain Laboratories	India	pass	1	1.58	1.32	1.17	not detected	no
A-075	A075/MM14/YG/01/C/GM	1312230111	GENTAMYCIN SULFATE	SHANGHAI MODERN H	China	pass	1.05	1.65	1.31	1.02	not detected	no
B-096	B-096/MM14/YG/02/C/GM	1312210111	GENTAMYCIN SULFATE	SHANGHAI MODERN H	China	pass	0.88	1.55	0.98	0.89	not detected	no
A-043	A043/MM14/YG/03/C/GM	GENTA3043	GENTAMIN Injection	SHIN POONG PHARM.C	Korea	pass	1.24	1.91	1.08	1.04	not detected	no
A-064	A064/MM14/YG/01/Ocl/GM	GENTA2020	GENTAMIN Injection	SHIN POONG PHARM.C	Korea	pass	0.76	1.78	1.06	1.12	not detected	no
A-083	A083/MM14/YG/02/HP/GM	GENTA4007	GENTAMIN Injection	SHIN POONG PHARM.C	Korea	pass	0.84	1.74	0.93	0.95	not detected	no
A-100	A100/MM14/YG/01/HG/GM	GENTA3049	GENTAMIN Injection	SHIN POONG PHARM.C	Korea	pass	0.85	1.83	1.07	1.04	not detected	no
A-035	A035/MM14/YG/01/Ocl/GM	304162	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	China	pass	1.05	1.83	1.35	1.26	not detected	no
A-040	A040/MM14/YG/01/C/GM	304152	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	China	pass	0.96	1.8	1.32	1.26	not detected	no
A-059	A059/MM14/YG/HP/GM	211342	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	China	pass	0.91	1.4	1.02	0.97	not detected	no
A-080	A080/MM14/YG/02/Ocl/GM	207252	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	1.02	1.84	1.36	1.19	not detected	no
A-105	A105/MM14/YG/02/HP/GM	211332	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	0.97	1.77	1.3	1.18	not detected	no
A-108	A108/MM14/YG/02/C/GM	304152	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	1.08	1.76	1.29	1.2	not detected	no
B-001	B-001/MM14/YG/01/HP/GM	304162	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	1.03	1.92	1.38	1.3	not detected	no
B-026	B-026/MM14/YG/01/C/GM	211342	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	1	1.7	1.27	1.18	not detected	no
B-028	B-028/MM14/YG/02/C/GM	207262	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	1.01	1.77	1.29	1.15	not detected	no
B-035	B-035/MM14/YG/01/HP/GM	304162	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	0.98	1.89	1.37	1.3	not detected	no
B-081	B-081/MM14/YG/01/O(c)/GM	211342	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	0.85	1.72	1.3	1.18	not detected	no
B-091	B-091/MM14/YG/00/W/GM	307031	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	0.98	1.89	1.37	1.3	not detected	no
B-095	B-095/MM14/YG/02/C/OM	211342	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	1.01	1.8	1.32	1.26	not detected	no
B-099	B-099/MM14/YG/103/C/GM	211342	GENTAMYCIN INJECTIC	SIU GUAN CHEM. IND. (	Taiwan	pass	1	1.18	1.28	1.2	not detected	no
A-053	A053/MM14/YG/02/HG/GM	311001	Genacyn	SQUARE PHARMACEUT	Bangladesl	pass	0.91	1.81	1.27	1.16	not detected	no
A-088	A088/MM14/YG/01/W/GM	404001	Genacyn	SQUARE PHARMACEUT	Bangladesl	pass	1.34	1.65	1.67	1.51	not detected	no
B-009	B-009/MM14/YG/02/O(c)/GM	208001	Genacyn	SQUARE PHARMACEUT	Bangladesl	pass	0.89	2	1.18	1.2	not detected	no
B-050	B-050/MM14/YG/02/C/GM	404001	Genacyn	SQUARE PHARMACEUT	Bangladesl	pass	1.22	1.5	1.47	1.33	not detected	no
A-023	A023/MM14/YG/04/C/GM	131227	Pai Genta	TIANJIN PHARMACEUT	China	pass	1	1.5	0.89	0.81	not detected	no
A-070	A070/MM14/YG/03/C/GM	1406173	Pai Genta	TIANJIN PHARMACEUT	China	pass	0.92	1.59	1.21	1.34	not detected	no
A-072	A-072/MM14/YG/01/HG/GM	121127	Pai Genta	TIANJIN PHARMACEUT	China	pass	0.9	1.48	1.26	1.09	not detected	no
B-048	B-048/MM14/YG/01/C/GM	1406183	Pai Genta	TIANJIN PHARMACEUT	China	pass	0.84	1.52	1.07	1.19	not detected	no
A-022	A022/MM14/YG/04/C/GM	140603	Gentamycin Sulfate inje	ZHANGFENG PHARMAC	China	pass	0.99	1.43	1.34	1.18	not detected	no
A-112	A112/MM14/YG/01/C/GM	140603	Gentamycin Sulfate inje	ZHANGFENG PHARMAC	China	pass	0.73	1.13	1.05	0.93	not detected	no
B-040	B-040/MM14/YG/01/HG/GM	140603	Gentamycin Sulfate inje	ZHANGFENG PHARMAC	China	pass	1.05	1.52	1.46	1.28	not detected	no
B-084	B-084/MM14/YG/02/C/GM	140602	Gentamycin Sulfate inje	ZHANGFENG PHARMAC	China	pass	1	1.49	1.4	1.29	not detected	no
A-003	A069/MM14/YG/03/C/GM	13032802	硫酸庆大霉素注射液	河南龙源药业股份有限	China	pass	0.84	1.05	1.21	1.15	not detected	no

Result of Microbial Assay [GM]

Serial No	Sample Code	Batch/Lot no	Trade name of the product	Name of Manufacturer	Manufacturing Country	Microbial assay	circle/cup (mm) ①	circle/cup (mm) ②	circle/cup (mm) ③	Potency (μg/mg)
A-069	A069/MM14/YG/02/C/GM	20140628	GENTAMICIN SULFATE INJE	BEVERLY HE	China	fail	QL	QL	QL	Under Quantitat
A-014	A014/MM14/YG/01/HG/GM	86GGA001	Gentamicin 80mg	Fresenius Kal	Vietnam	pass	3.12	3.09	3.08	1366
A-090	A090/MM14/YG/02/W/GM	86HBA002	Gentamicin 80mg	Fresenius Kal	Vietnam	pass	3.16	3.17	2.99	1202
B-064	B-064/MM14/YG/01/O(c)/GM	86HBA001	Gentamicin 80mg	Fresenius Kal	Vietnam	pass	3.12	3.12	3.14	1231
A-020	A020/MM14/YG/01/C/GM	20130406	GENTAMYCIN SULFATE INJE	HENAN DEKA	China	fail	1	1	1	Under Quantitat
A-077	A077/MM14/YG/02/C/GM	20130406	GENTAMYCIN SULFATE INJE	HENAN DEKA	China	fail	1	1	1	Under Quantitat
B-051	B-051/MM14/YG/03/C/GM	MM20140725	GENTAMEDINE	KUNMING PH	China	pass	3.1	3.06	2.89	1090
PA-003	PA003/MM14/YG/01/C/GM	MM20140528	GENTAMEDINE	KUNMING PH	China	pass	2.68	2.68	2.69	1818
B-018	B-018/MM14/YG/04/C/GM	14351904	MERIGENTA	MERCURY La	India	pass	3.06	3.45	2.82	1203
B-019	B-019/MM14/YG/05/C/GM	14351902	MERIGENTA	MERCURY La	India	pass	2.59	2.87	2.77	1429
B-075	B-075/MM14/YG/01/HG/GM	14351903	MERIGENTA	MERCURY La	India	pass	3.09	3.2	3.24	1414
B-022	B-022/MM14/YG/06/C/GM	62040	GENTAMICIN INJECTION	Myanma Phar	Myanmar	pass	3.05	2.92	2.75	997
B-068	B-068/MM14/YG/01/C/GM	1179084	GENTAMICIN INJECTION	Myanma Phar	Myanmar	pass	2.78	2.71	3.3	2987
B-105	B-105/MM14/YG/01/HG/GM	0787M1	GENTAMICIN INJECTION	Myanma Phar	Myanmar	pass	3.16	3.02	2.89	1100
B-058	B-058/MM14/YG/01/HP/GM	7874C5	GENTAMICIN INJECTION	No.(1)Pharma	Myanmar	pass	2.66	3.03	2.69	2332
B-060	B-060/MM14/YG/01/HP/GM	7272C5	GENTAMICIN INJECTION	No.(1)Pharma	Myanmar	pass	2.86	3.23	2.96	1213
A-004	A004/MM14/YG/04/HG/GM	1874094	GENTAMICIN INJECTION	No.(2)Pharma	Myanmar	pass	3.41	3.22	3.08	1364
A-024	A024/MM14/YG/04/C/GM	8073053	GENTAMICIN INJECTION	No.(2)Pharma	Myanmar	pass	2.73	2.67	2.75	1966
A-044	A044/MM14/YG/04/C/GM	161040	GENTAMICIN INJECTION	No.(2)Pharma	Myanmar	pass	2.93	3.15	2.79	1017
A-111	A111/MM14/YG/01/C/GM	1572084	GENTAMICIN INJECTION	No.(2)Pharma	Myanmar	pass	3.33	3.08	3.23	1597
B-085	B-085/MM14/YG/02/C/GM	160040	GENTAMICIN INJECTION	No.(2)Pharma	Myanmar	pass	2.32	2.35	2.67	922
B-107	B-107/MM14/YG/02/HG/GM	162040	GENTAMICIN INJECTION	No.(2)Pharma	Myanmar	pass	2.91	3.09	2.9	1961
B-069	B-069/MM14/YG/01/C/GM	612010	GENTAMICIN	PHARBACO	Vietnam	pass	2.83	3.03	2.82	2812
B-072	B-072/MM14/YG/01/HG/GM	RG321	REGENTA	Regain Labor	India	pass	3	3.19	3.18	1326
B-109	B-109/MM14/YG/01/C/GM	RG314	REGENTA	Regain Labor	India	pass	2.49	2.31	2.43	1160
A-075	A075/MM14/YG/01/C/GM	1312230111	GENTAMYCIN SULFATE INJE	SHANGHAI M	China	pass	2.8	3.07	2.96	1919
B-096	B-096/MM14/YG/02/C/GM	1312210111	GENTAMYCIN SULFATE INJE	SHANGHAI M	China	pass	2.79	2.83	2.97	2692
A-043	A043/MM14/YG/03/C/GM	GENTA3043	GENTAMIN Injection	SHIN POONG	Korea	pass	2.59	2.67	2.47	1176
A-064	A064/MM14/YG/01/Ocl/GM	GENTA2020	GENTAMIN Injection	SHIN POONG	Korea	pass	2.93	2.73	2.76	2402
A-083	A083/MM14/YG/02/HP/GM	GENTA4007	GENTAMIN Injection	SHIN POONG	Korea	pass	2.9	2.79	3.08	1884
A-100	A100/MM14/YG/01/HG/GM	GENTA3049	GENTAMIN Injection	SHIN POONG	Korea	pass	2.69	2.9	2.83	1650
A-035	A035/MM14/YG/01/Ocl/GM	304162	GENTAMYCIN INJECTION	SIU GUAN C	China	pass	2.39	2.71	2.84	1326
A-040	A040/MM14/YG/01/C/GM	304152	GENTAMYCIN INJECTION	SIU GUAN C	China	pass	2.48	2.26	2.43	810
A-059	A059/MM14/YG/HP/GM	211342	GENTAMYCIN INJECTION	SIU GUAN C	China	pass	2.51	2.54	2.55	1338
A-080	A080/MM14/YG/02/Ocl/GM	207252	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.69	2.75	2.44	1558
A-105	A105/MM14/YG/02/HP/GM	211332	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.54	2.56	2.42	1273
A-108	A108/MM14/YG/02/C/GM	304152	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.6	2.47	2.66	1427
B-001	B-001/MM14/YG/01/HP/GM	304162	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.81	3.02	2.82	2143
B-026	B-026/MM14/YG/01/C/GM	211342	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.91	2.92	3.13	1823
B-028	B-028/MM14/YG/02/C/GM	207262	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.71	2.78	2.74	1820
B-035	B-035/MM14/YG/01/HP/GM	304162	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.5	2.61	2.63	1442
B-081	B-081/MM14/YG/01/O(c)/GM	211342	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	3.29	3.46	3.26	1448
B-091	B-091/MM14/YG/00/W/GM	307031	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.95	2.86	2.82	1643
B-095	B-095/MM14/YG/02/C/OM	211342	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	2.83	2.81	2.84	2008
B-099	B-099/MM14/YG/103/C/GM	211342	GENTAMYCIN INJECTION	SIU GUAN C	Taiwan	pass	3.28	3.01	2.95	2591
A-053	A053/MM14/YG/02/HG/GM	311001	Genacyn	SQUARE PH	Bangladesh	pass	2.64	2.36	2.51	1299
A-088	A088/MM14/YG/01/W/GM	404001	Genacyn	SQUARE PH	Bangladesh	pass	3.09	2.84	3.03	1158
B-009	B-009/MM14/YG/02/O(c)/GM	208001	Genacyn	SQUARE PH	Bangladesh	pass	2.52	2.76	2.58	1231
B-050	B-050/MM14/YG/02/C/GM	404001	Genacyn	SQUARE PH	Bangladesh	pass	3.37	3.03	2.9	989
A-023	A023/MM14/YG/04/C/GM	131227	Pai Genta	TIANJIN PHA	China	pass	2.93	3.07	2.91	1075
A-070	A070/MM14/YG/03/C/GM	1406173	Pai Genta	TIANJIN PHA	China	pass	2.85	2.79	3.28	1799
A-072	A-072/MM14/YG/01/HG/GM	121127	Pai Genta	TIANJIN PHA	China	pass	2.74	2.97	2.85	1609
B-048	B-048/MM14/YG/01/C/GM	1406183	Pai Genta	TIANJIN PHA	China	pass	2.48	2.54	2.35	973
A-022	A022/MM14/YG/04/C/GM	140603	Gentamycin Sulfate injection	ZHANGFENG	China	pass	2.94	2.34	3.04	755
A-112	A112/MM14/YG/01/C/GM	140603	Gentamycin Sulfate injection	ZHANGFENG	China	pass	2.2	2.54	2.79	1309
B-040	B-040/MM14/YG/01/HG/GM	140603	Gentamycin Sulfate injection	ZHANGFENG	China	pass	3.37	3.27	3.06	1251
B-084	B-084/MM14/YG/02/C/GM	140602	Gentamycin Sulfate injection	ZHANGFENG	China	pass	2.82	2.73	2.61	1393
A-003	A069/MM14/YG/03/C/GM	13032802	硫酸庆大霉素注射液	河南龙源药业	China	pass	3.05	2.91	3.04	1465

** All GM samples were passed in sterility and endotoxin tests

Annex 1.8

CXM dissolution test

ID	Serial No.	Sample Code	Trade name of the product	Name of Manufacturer	Manufacturing Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Initial Judge	New Judge
3	A-005	A005/MM14/YG/01/HG/	SPIZEF	Orchid HEALTHCA	India	101.01	96.57	95.96	96.92	99.78	95.69	97.65	2.2	2.26	Pass	
4	A-006	A006/MM14/YG/01/HG/	Zinnat	GlaxoSmithKline	UK	77.86	86.26	87.94	87.54	91.17	91.77	87.09	5.01	5.75	Pass	
5	A-007	A007/MM14/YG/01/HG/	ZIFTUM 250	Alkem Laboratori	India	94.80	96.21	95.20	98.97	95.40	97.02	96.27	1.54	1.60	Pass	
6	A-016	A016/MM14/YG/01/HG/	ZINNASAV-250	SAVIOUR PHARMA	India	86.13	86.73	80.62	77.52	85.79	82.70	83.25	3.66	4.39	Pass	
7	A-017	A017/MM14/YG/01/HG/	ZIFATIL-250	Galpha Laborato	India	108.91	95.81	110.33	106.09	107.70	113.48	107.05	6.06	5.66	Pass	
8	A-018	A018/MM14/YG/01/HG/	CETIL	LUPIN LTD.	India	100.74	93.64	93.71	101.42	102.10	97.87	98.25	3.82	3.89	Pass	
9	A-019	A019/MM14/YG/01/HG/	FUROCEF	RENATA LIMITED	Bangladesh	69.59	77.86	74.23	86.87	83.51	82.50	79.09	6.43	8.13	Pass	
10	A-025	A025/MM14/YG/04/C/C	SPIZEF	Orchid HEALTHCA	India	84.11	96.75	94.19	78.87	95.81	91.57	90.22	7.18	7.96	Pass	
11	A-030	A030/MM14/YG/02/C/C	RUFEX-250	Global Pharma H	India	80.68	87.20	71.81	60.60	86.93	77.86	77.52	10.11	13.05	Fail	Pass
12	A-036	A036/MM14/YG/01/Ocl	ZIFTUM 250	Alkem Laboratori	India	100.40	94.87	87.70	95.28	92.61	92.96	93.97	4.15	4.41	Pass	
13	A-037	A037/MM14/YG/01/Ocl/	Cefusan 250	SRS pharmaceuti	India	94.46	94.66	96.71	95.89	95.55	93.84	95.19	1.05	1.11	Pass	
14	A-048	A048/MM14/YG/06/C/C	RUFEX-250	Global Pharma H	India	66.77	63.95	65.56	66.37	66.57	68.99	66.37	1.65	2.48	Fail	Pass
15	A-052	A052/MM14/YG/02/HG/	ZIFTUM 250	Alkem Laboratori	India	96.81	97.35	98.50	97.22	100.85	101.05	98.63	1.88	1.91	Pass	
16	A-054	A054/MM14/YG/02/C/C	ZIFTUM 250	Alkem Laboratori	India	96.88	100.24	93.79	97.82	98.63	98.83	97.70	2.22	2.27	Pass	
17	A-057	A057/MM14/YG/01/HP/	RUFEX-250	Global Pharma H	India	51.24	71.52	79.71	71.72	79.92	72.54	71.11	10.48	14.73	Fail	Pass
18	A-058	A058/MM14/YG/HP/CX	Zinnat	GlaxoSmithKline	UK	94.19	91.57	91.17	88.14	96.81	93.39	92.55	2.96	3.20	Pass	
19	A-063	A063/MM14/YG/01/Ocl/	ZIFTUM 250	ALKEM LABORATO	India	101.01	93.84	91.59	92.00	94.39	95.89	94.79	3.43	3.62	Pass	
20	A-068	A068/MM14/YG/02/C/C	RUFEX-250	Global Pharma H	India	78.46	80.68	70.40	63.34	69.59	71.61	72.35	6.32	8.74	Fail	Pass
21	A-071	A071/MM14/YG/01/HG/	ZIFTUM 250	ALKEM LABORATO	India	96.61	96.68	104.14	97.82	92.78	94.40	97.07	3.91	4.03	Pass	
22	A-074	A074/MM14/YG/01/C/C	ZIFTUM 250	ALKEM LABORATO	India	90.77	91.98	87.74	91.17	88.88	86.73	89.54	2.08	2.32	Pass	
23	A-079	A079/MM14/YG/02/Ocl/	RUFEX-250	Global Pharma H	India	64.69	62.27	63.95	81.09	58.91	62.00	65.48	7.90	12.07	Fail	Pass
24	A-085	A085/MM14/YG/02/HP/	RUFEX-250	Global Pharma H	India	64.35	59.23	66.88	59.03	63.94	70.22	63.94	4.35	6.80	Fail	Pass
25	A-086	A086/MM14/YG/02/HP/	Zinnat	GlaxoSmithKline	UK	82.97	81.89	85.32	89.62	85.12	87.94	85.48	2.92	3.41	Pass	
26	A-089	A089/MM14/YG/01/W/C	Cefotil	SQUARE PHARMA	Bangladesh	BP	–	–	–	–	–	–	–	–	–	
27	A-095	A095/MM14/YG/03/W/C	KEFROX	CCL Pharmaceutic	Pakistan	BP	–	–	–	–	–	–	–	–	–	
28	A-099	A099/MM14/YG/01/HG/	RUFEX-500	Global Pharma H	India	65.56	57.43	52.65	66.16	62.13	64.55	61.41	5.34	8.70	Fail	Pass
29	A-102	A102/MM14/YG/01/Ocl/	CETIL	LUPIN LTD.	India	73.42	72.28	70.60	76.05	70.80	69.66	72.14	2.33	3.24	Pass	
30	A-104	A104/MM14/YG/02/HP/	ZIFTUM 250	ALKEM LABORATO	India	106.90	103.07	100.65	105.99	99.03	106.29	103.65	3.28	3.16	Pass	
32	B-002	B-002/MM14/YG/01/HP/	ZIFTUM 250	Alkem Laboratori	India	126.66	131.50	131.09	122.42	131.30	136.54	129.92	4.83	3.71	Pass	
33	B-003	B-003/MM14/YG/01/HP/	SPIZEF	Orchid HEALTHCA	India	98.43	96.21	94.60	92.78	96.41	94.19	95.44	1.99	2.08	Pass	
34	B-004	B-004/MM14/YG/01/HP/	CETIL	LUPIN LTD.	India	73.42	74.84	73.89	75.31	80.48	74.23	75.36	2.60	3.44	Pass	
35	B-023	B-023/MM14/YG/07/C/C	RUFEX	Global Pharma H	India	62.33	64.15	62.13	65.36	65.09	63.34	63.73	1.37	2.14	Fail	Pass
36	B-027	B-027/MM14/YG/01/C/C	Zinnat	GlaxoSmithKline	UK	91.77	93.19	89.96	87.74	94.19	93.59	91.74	2.48	2.70	Pass	
37	B-029	B-029/MM14/YG/02/C/C	ZIFTUM 250	Alkem Laboratori	India	80.88	82.50	81.15	89.62	85.12	87.94	84.54	3.65	4.32	Pass	
38	B-030	B-030/MM14/YG/08/C/C	Zinnat	GlaxoSmithKline	UK	89.54	79.58	89.54	84.29	86.06	82.99	85.33	3.89	4.56	Pass	
39	B-031	B-031/MM14/YG/08/C/C	ZIFTUM 250	Alkem Laboratori	India	98.83	97.02	97.42	97.22	101.25	96.41	98.02	1.77	1.81	Pass	
40	B-034	B-034/MM14/YG/01/HP/	ZIFTUM 250	Alkem Laboratori	India	95.14	97.46	98.14	92.41	96.51	96.92	96.10	2.07	2.15	Pass	
41	B-038	B-038/MM14/YG/01/HP/	ZIFTUM 250	Alkem Laboratori	India	127.26	122.02	127.47	124.04	122.09	123.84	124.45	2.41	1.94	Pass	
42	B-042	B-042/MM14/YG/01/HG	ZIFATIL	Galpha Laborato	India	88.93	88.31	84.83	87.43	90.36	90.77	88.44	2.16	2.45	Pass	
43	B-044	B-044/MM14/YG/01/HG	Zinmax	DOMESCO MEDIC	VietNam	90.77	91.17	92.38	88.55	89.15	89.56	90.26	1.43	1.58	Pass	
44	B-047	B-047/MM14/YG/01/C/C	RUFEX	Global Pharma H	India	60.52	59.51	59.71	62.94	60.52	60.32	60.59	1.23	2.03	Fail	Pass
45	B-052	B-052/MM14/YG/01/HP/	CETIL	LUPIN LTD.	India	109.12	107.50	103.74	100.18	112.14	105.89	106.43	4.19	3.93	Pass	
46	B-053	B-053/MM14/YG/01/HP/	Zinnat	GlaxoSmithKline	UK	88.75	94.19	86.13	79.67	74.43	88.35	85.25	7.08	8.31	Pass	
47	B-063	B-063/MM14/YG/01/O(c	ZIFTUM 250	Alkem Laboratori	India	93.43	88.93	105.52	98.14	93.23	103.13	97.06	6.38	6.57	Pass	
48	B-066	B-066/MM14/YG/01/C/C	ZIFTUM 250	Alkem Laboratori	India	91.59	87.90	96.92	95.69	94.25	100.60	94.49	4.39	4.65	Pass	
49	B-067	B-067/MM14/YG/01/C/C	RUFEX-250	Global Pharma H	India	84.92	72.82	78.46	81.96	77.66	79.67	79.25	4.10	5.18	Pass	
50	B-076	B-076/MM14/YG/01/HG	ZIFTUM 250	Alkem Laboratori	India	99.23	92.98	93.99	95.60	94.19	96.21	95.37	2.22	2.33	Pass	
51	B-079	B-079/MM14/YG/01/O(c	ZIFTUM 250	Alkem Laboratori	India	93.39	93.99	90.36	91.57	92.98	95.47	92.96	1.80	1.94	Pass	
52	B-080	B-080/MM14/YG/01/O(c	Zinnat	GlaxoSmithKline	UK	91.37	89.76	83.10	91.77	86.33	90.97	88.88	3.45	3.88	Pass	
53	B-086	B-086/MM14/YG/03/C/C	Zinnat	GlaxoSmithKline	UK	77.26	88.61	85.19	80.88	82.50	81.15	82.60	3.91	4.73	Pass	
54	B-089	B-089/MM14/YG/04/W/	Zinnat	GlaxoSmithKline	UK	77.66	89.89	75.64	81.69	73.02	78.67	79.43	5.89	7.42	Pass	
55	B-093	B-093/MM14/YG/01/C/C	RUFEX	Global Pharma H	India	65.56	64.75	87.54	85.12	81.49	89.76	79.04	11.10	14.04	Fail	Pass
56	B-100	B-100/MM14/YG/04/C/C	ZIFTUM 250	Alkem Laboratori	India	100.04	98.43	100.04	98.83	96.41	102.06	99.30	1.90	1.91	Pass	
57	B-101	B-101/MM14/YG/05/C/C	Zinnat	GlaxoSmithKline	UK	89.15	85.52	92.51	88.35	89.15	91.17	89.31	2.41	2.70	Pass	
58	B-102	B-102/MM14/YG/02/C/C	Zinnat	GlaxoSmithKline	UK	83.91	89.62	87.81	88.28	95.60	91.37	89.43	3.91	4.37	Pass	
59	B-104	B104/MM14/YG/01/HG/	ZIFTUM 250	Alkem Laboratori	India	94.80	98.23	90.36	93.99	96.01	92.18	94.26	2.78	2.95	Pass	
60	B-111	B111/MM14/YG/02/C/C	RUFEX-250	Global Pharma H	India	76.91	67.63	74.18	89.13	89.13	85.99	80.50	8.92	11.08	Pass	
1	PA-001	PA001/MM14/YG/01/C/C	ZIFTUM 250	Alkem Laboratori	India	158.05	134.52	153.14	152.94	136.54	146.22	146.90	9.60	6.53	Pass	
2	PA-002	PA002/MM14/YG/01/C/C	SPIZEF	Orchid HEALTHCA	India	73.83	98.97	100.24	97.22	85.79	83.04	89.85	10.63	11.83	Pass	
31	PB-001	PB-001/MM14/YG/01/O(	ZINNASAV-250	SAVIOUR PHARMA	India	75.96	82.78	83.19	85.86	82.58	81.35	81.95	3.29	4.02	Pass	

CXM content uniformity 1st stage

% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	% of Quantity Tablet 7	% of Quantity Tablet 8	% of Quantity Tablet 9	% of Quantity Tablet 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge	New Judge AV=18
104.92	104.54	100.00	102.70	95.88	99.40	94.86	105.87	101.22	96.94	100.6	3.9	3.9	9.372893126	Pass	
104.21	103.39	98.63	97.51	93.65	103.10	106.08	98.50	95.83	102.27	100.3	4.1	4.0	9.731768808	Pass	
102.27	103.86	100.48	102.58	98.18	97.12	100.36	100.98	97.48	92.73	99.6	3.3	3.3	7.89	Pass	
92.41	93.57	91.85	95.51	95.75	90.01	89.77	84.34	88.41	101.55	92.3	4.7	5.1	17.48	Fail	Pass
84.42	99.25	100.84	85.26	90.85	90.97	97.08	91.92	93.14	92.91	92.7	5.4	5.8	18.72	Fail	Fail
85.61	97.53	104.85	104.61	90.77	107.86	98.31	94.87	97.54	98.02	98.0	6.7	6.8	16.58	Fail	Pass
99.58	97.87	93.20	95.87	93.71	103.43	100.62	95.39	98.09	95.14	97.3	3.2	3.3	9.00	Pass	
94.08	101.01	89.89	94.86	93.99	95.64	99.03	101.53	94.92	92.86	95.8	3.7	3.8	11.55	Pass	
92.98	91.66	89.14	90.87	92.74	88.74	88.45	86.30	82.74	82.84	88.6	3.7	4.2	18.76	Fail	Fail
104.08	102.32	92.47	95.41	111.73	93.88	93.39	101.14	92.26	94.69	98.1	6.4	6.6	15.45	Fail	Pass
91.27	93.27	96.13	88.28	98.09	91.63	91.59	94.10	87.74	79.11	91.1	5.3	5.8	20.06	Fail	Fail
95.65	100.96	82.79	86.92	84.50	92.64	87.53	87.83	84.09	83.79	88.7	5.9	6.7	24.08	Fail	Fail
92.28	99.85	94.71	96.54	95.82	98.57	99.74	103.67	107.73	105.66	99.5	5.0	5.0	11.90	Pass	
101.48	100.22	91.88	103.28	95.38	105.52	97.11	98.08	92.65	95.07	98.1	4.5	4.6	11.28	Pass	
87.87	87.87	87.65	82.96	87.90	82.50	85.36	79.08	77.86	80.46	84.0	3.9	4.7	23.95	Fail	Fail
95.38	104.18	100.01	98.10	103.39	99.45	93.58	100.25	90.67	91.76	97.7	4.7	4.8	12.04	Pass	
99.58	95.59	96.90	102.68	100.60	103.08	94.12	99.93	98.40	95.48	98.6	3.1	3.1	7.38	Pass	
85.13	80.97	74.62	–	–	–	–	–	–	–	80.2	–	–	–	–	
107.29	97.04	100.25	99.21	101.42	104.80	95.76	99.53	94.60	89.71	99.0	5.1	5.1	12.13	Pass	
105.17	99.99	101.85	103.65	98.37	100.92	98.68	93.11	93.86	98.67	99.4	3.8	3.9	9.21	Pass	
86.23	86.08	82.00	86.17	84.76	88.14	83.31	89.02	81.19	82.07	84.9	2.7	3.2	20.05	Fail	Fail
98.68	88.40	99.10	101.87	98.65	93.01	98.22	95.66	96.45	97.29	96.7	3.7	3.9	10.77	Pass	
94.85	92.47	90.91	95.96	99.71	94.09	96.69	97.74	93.76	94.46	95.1	2.6	2.7	9.60	Pass	
97.95	97.60	93.43	92.10	101.08	87.19	96.73	96.72	93.55	94.45	95.1	3.8	4.0	12.63	Pass	
89.41	99.51	95.97	94.42	103.65	96.10	90.11	97.75	94.44	90.99	95.2	4.4	4.6	13.88	Pass	
79.62	80.37	82.34	80.60	76.43	78.62	81.50	79.29	78.70	75.53	79.3	2.1	2.7	24.28	Fail	Fail
98.44	99.04	95.46	93.58	98.00	95.74	100.25	97.12	98.56	87.30	96.3	3.7	3.9	11.12	Pass	
103.02	98.07	99.18	103.84	101.83	103.11	94.54	97.96	102.81	97.01	100.1	3.2	3.2	7.67	Pass	
96.55	104.47	106.58	100.60	100.41	102.25	90.34	103.61	96.69	99.31	100.1	4.7	4.7	11.27	Pass	
94.9	96.3	96.4	94.2	99.8	100.9	95.0	95.7	91.2	103.1	96.7	3.5	3.6	10.22	Pass	
98.99	100.25	99.81	95.66	94.94	97.36	89.83	90.59	94.11	93.58	95.5	3.6	3.8	11.71	Pass	
86.47	88.94	86.99	95.59	93.94	92.55	73.24	90.08	89.30	82.01	87.9	6.5	7.4	26.13	Fail	Fail
96.26	93.06	95.03	91.98	95.18	90.38	93.66	86.06	98.76	92.34	93.3	3.5	3.7	13.57	Pass	
98.08	99.17	97.64	88.44	89.52	93.13	83.94	84.61	78.65	95.15	90.8	6.9	7.6	24.34	Fail	Fail
97.84	98.27	109.33	101.97	98.36	104.72	97.52	111.74	108.12	93.15	102.1	6.1	6.0	15.27	Pass	
96.67	101.02	94.08	96.38	93.86	95.06	93.75	96.25	96.24	97.52	96.1	2.2	2.3	7.63	Pass	
101.07	100.73	104.94	106.81	101.49	97.11	102.96	106.33	102.82	102.79	102.7	2.9	2.8	8.11	Pass	
105.30	92.74	104.55	105.08	97.92	98.05	98.24	100.54	98.83	98.10	99.9	4.0	4.0	9.59	Pass	
83.66	84.52	86.32	91.22	84.44	85.86	91.58	84.65	93.10	80.82	86.6	4.0	4.6	21.48	Fail	Fail
102.47	102.35	102.44	104.48	103.97	103.72	102.78	98.97	97.20	96.30	101.5	2.9	2.9	6.98	Pass	
71.12	69.88	88.62	76.65	74.10	77.86	88.15	85.61	73.36	74.00	77.9	7.0	9.0	37.37	Fail	Fail
91.71	97.36	88.44	93.86	88.52	96.88	92.86	90.31	92.94	92.51	92.5	3.0	3.3	13.24	Pass	
104.46	85.18	85.58	83.73	90.96	104.88	89.09	90.42	102.98	103.08	94.0	8.8	9.3	25.50	Fail	Fail
98.72	91.94	97.51	92.91	97.18	91.92	109.19	92.38	98.29	102.77	97.3	5.5	5.7	14.50	Pass	
97.47	99.41	97.77	99.32	92.59	92.40	94.94	95.56	96.13	101.41	96.7	2.9	3.0	8.88	Pass	
97.63	100.15	107.00	101.46	107.64	106.13	101.37	101.88	100.85	101.86	102.6	3.2	3.2	8.89	Pass	
97.22	96.14	92.13	89.04	90.90	91.00	95.82	93.73	84.56	92.74	92.3	3.8	4.1	15.21	Pass	
101.08	94.44	98.21	99.11	103.97	102.67	97.27	97.77	97.49	97.75	99.0	2.8	2.9	6.80	Pass	
97.64	99.42	97.71	100.36	97.58	96.02	98.42	96.52	96.50	96.74	97.7	1.4	1.4	4.12	Pass	
92.29	98.58	98.56	91.81	102.01	90.37	90.05	93.33	92.23	94.00	94.3	4.0	4.3	13.81	Pass	
109.93	105.57	104.26	115.00	103.68	107.96	107.55	110.73	101.57	102.22	106.8	4.2	4.0	15.48	Pass	
88.76	91.12	80.84	80.41	75.56	87.75	83.93	82.01	89.50	86.58	84.6	4.9	5.8	25.68	Fail	Fail
93.01	94.13	107.34	91.54	94.24	102.22	93.05	92.89	89.85	90.01	94.8	5.6	5.9	17.08	Fail	Pass
101.68	103.63	103.61	99.44	102.50	115.40	101.56	97.35	95.65	98.59	101.9	5.4	5.3	13.47	Pass	
94.09	96.03	98.31	97.15	93.26	92.67	95.69	99.97	95.30	96.11	95.9	2.2	2.3	8.01	Pass	
99.74	105.46	105.23	100.22	101.84	95.14	97.11	101.63	90.14	102.08	99.9	4.7	4.7	11.22	Pass	
77.76	80.96	83.08	77.55	76.53	76.92	78.97	79.20	74.70	77.48	78.3	2.4	3.0	25.88	Fail	Fail
93.01	94.13	101.56	91.54	94.24	102.22	93.05	92.89	89.85	90.01	94.3	4.3	4.6	14.57	Pass	
103.65	100.90	102.00	99.25	97.83	96.97	102.27	102.52	93.13	99.91	99.8	3.2	3.2	7.64	Pass	
88.20	90.25	93.58	92.14	90.62	79.25	94.40	95.94	85.54	88.40	89.83	4.87	5.42	20.36	Fail	Fail

CXM content uniformity 2nd stage

% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	% of Quantity Tablet 7	% of Quantity Tablet 8	% of Quantity Tablet 9	% of Quantity Tablet 10	% of Quantity Tablet 11	% of Quantity Tablet 12	% of Quantity Tablet 13	% of Quantity Tablet 14	% of Quantity Tablet 15	% of Quantity Tablet 16	% of Quantity Tablet 17	% of Quantity Tablet 18	% of Quantity Tablet 19	% of Quantity Tablet 20	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge for Content Uniformity	New Judge for Content Uniformity	Kanazawa Univ. Quantity test	Judge	New Judge	Kanazawa Univ. Quantity test 2nd	Kanazawa Univ. Final Judge	New Final Judge	AI I	New AI I
																								Pass		100.63	Pass		-	Pass			Pass
																								Pass		100.32	Pass		-	Pass			Pass
																								Pass		99.60	Pass		-	Pass			Pass
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Pass		99.32	Pass		88.96	Fail	Pass	Fail	Pass
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Fail	92.66	Pass		-	Pass		Fail	Fail
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Pass		98.00	Pass		-	Pass		Fail	Pass
																								Pass		97.29	Pass		-	Pass			Pass
																								Pass		95.78	Pass		-	Pass			Pass
92.27	92.42	92.10	92.27	92.68	91.66	88.43	90.69	83.91	80.84	91.06	90.78	85.74	85.97	87.09	82.13	85.49	81.53	83.53	83.05	88.51	3.94	4.46	17.88	Fail	Pass	88.65	Fail	Pass	88.51	Fail	Pass	Fail	Pass
103.74	97.31	100.95	96.99	97.34	94.32	93.53	99.38	94.32	100.71	97.08	90.13	99.63	93.98	97.15	83.28	93.22	92.56	90.18	97.62	94.15	5.19	5.51	14.72	Pass		98.14	Pass		101.90	Pass		Pass	
106.26	97.80	101.48	92.52	100.54	104.06	101.64	85.36	104.57	99.83	88.92	94.43	94.28	95.97	91.60	94.93	95.01	93.71	104.98	91.35	94.22	6.92	7.34	18.11	Fail	Fail	91.12	Pass		94.15	Pass		Pass	
																								Pass		88.67	Fail	Pass	94.22	Pass		Fail	Fail
																								Pass		99.46	Pass		-	Pass		Pass	
																								Pass		98.07	Pass		-	Pass		Pass	
80.29	84.28	77.86	84.57	81.54	82.89	80.56	76.34	77.11	77.13	83.49	83.87	86.29	80.73	85.28	83.90	86.82	83.35	82.47	86.22	82.88	3.48	4.20	22.58	Fail	Fail	83.95	Fail	Pass	82.88	Fail	Pass	Fail	Fail
																								Pass		97.68	Pass		-	Pass			
																								Pass		98.64	Pass		-	Pass		Pass	
																								Fail		80.24	Fail	Pass	-	Fail	Pass	Fail	Pass
																								Pass		98.96	Pass		-	Pass			
																								Pass		99.43	Pass		-	Pass		Pass	
93.91	93.25	92.28	91.09	92.01	88.91	88.93	87.13	85.26	84.35	80.02	81.23	81.78	80.43	80.19	85.20	83.08	81.62	79.76	82.18	85.72	4.24	4.95	21.27	Fail	Fail	84.90	Fail	Pass	85.72	Fail	Pass	Fail	Fail
																								Pass		96.73	Pass		-	Pass			
																								Pass		95.06	Pass		-	Pass		Pass	
																								Pass		95.08	Pass		-	Pass		Pass	
																								Pass		95.24	Pass		-	Pass		Pass	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Fail	79.30	Fail	Pass	79.30	Fail	Pass	Fail	Fail
																								Pass		96.35	Pass		-	Pass			
																								Pass		100.14	Pass		-	Pass		Pass	
																								Pass		100.08	Pass		-	Pass		Pass	
																								Pass		96.72	Pass		-	Pass		Pass	
																								Pass		95.51	Pass		-	Pass		Pass	
																								Fail	Fail	87.91	Fail	Pass	87.91	Fail	Pass	Fail	Fail
																								Pass		93.27	Pass		-	Pass			
																								Pass		90.84	Pass		98.84	Pass		Pass	
																								Pass		102.10	Pass		-	Pass		Pass	
																								Pass		96.08	Pass		-	Pass		Pass	
																								Pass		102.71	Pass		-	Pass		Pass	
																								Pass		99.93	Pass		-	Pass		Pass	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Fail	86.61	Fail	Pass	86.61	Fail	Pass	Fail	Fail
																								Pass		101.47	Pass		-	Pass		Pass	
																								Fail	Fail	77.93	Fail	Pass	77.93	Fail	Pass	Fail	Fail
																								Pass		92.54	Pass		-	Pass			
106.32	96.25	95.82	97.59	99.85	102.09	97.49	91.39	98.72	96.62	92.69	93.54	91.32	91.09	96.74	99.63	93.44	97.31	92.81	97.83	95.20	6.01	6.31	15.32	Pass		94.04	Pass		95.20	Pass		Pass	
																								Pass		97.28	Pass		-	Pass		Pass	
																								Pass		96.70	Pass		-	Pass		Pass	
																								Pass		102.60	Pass		-	Pass		Pass	
																								Pass		92.33	Pass		-	Pass		Pass	
																								Pass		98.38	Pass		-	Pass		Pass	
																								Pass		97.69	Pass		-	Pass		Pass	
																								Pass		94.32	Pass		-	Pass		Pass	
																								Pass		106.85	Pass		-	Pass		Pass	
92.16	91.21	87.91	88.03	88.11	86.34	86.50	83.10	88.83	91.62	84.15	84.91	76.84	79.15	85.28	78.81	85.54	81.09	78.94	82.78	85.26	4.52	5.31	22.29	Fail	Fail	84.65	Fail	Pass	85.26	Fail	Pass	Fail	Fail
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Pass	94.83	Pass		-	Pass		Fail	Pass
																								Pass		101.94	Pass		-	Pass		Pass	
																								Pass		95.14	Pass		-	Pass		Pass	
																								Pass		99.86	Pass		-	Pass		Pass	
93.21	89.27	87.18	90.76	86.50	86.94	88.76	92.50	88.72	82.25	85.54	83.32	82.14	75.51	85.60	78.09	77.88	79.58	81.52	83.49	82.84	5.17	6.25	26.01	Fail	Fail	78.32	Fail	Pass	82.84	Fail	Pass	Fail	Fail
																								Pass		94.25	Pass		-	Pass		Pass	
																								Pass		99.84	Pass		-	Pass		Pass	
85.84	88.33	107.07	89.15	94.20	89.80	87.21	89.31	87.72	84.92	90.39	84.84	89.89	95.62	94.75	99.33	94.43	79.50	89.28	96.57	90.56	5.58	6.16	19.11	Fail	Fail	89.83	Pass		90.56	Pass		Fail	Fail

OM Dissolution test BP: 1st stage acid resistance stage

ID	Serial No .	Sample Code	Trade name of the	Name of Manufacturer	Manufactu	% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	New Judge 10% *1.2= 12% dissolved
27	A-096	A096/MM14/YG/	Omep-20	ARISTOPHARMA LTD.	Banglade	22.3	10.4	8.9	11.6	9.6	10.2	12.2	5.0	41.4	Fail	Fail
189	B-065	B-065/MM14/YG/	Omep	ARISTOPHARMA LTD.	Banglade	11.1	11.3	10.9	11.0	11.2	10.9	11.1	0.2	1.7	Fail	Pass
23	A-076	A076/MM14/YG/	ASMOZOL-20	ASMOH LABORATORIES LTD.	India	1.4	1.4	1.4	1.4	1.4	1.4	1.4	0.0	0.0	Pass	
215	B-092	B-092/MM14/YG/	OMEPREN	BLUE CROSS LABORATORIES LTD.	India	2.5	2.4	1.8	1.1	1.2	1.2	1.7	0.6	36.5	Pass	
221	B-098	B-098/MM14/YG/	OMEPREN	BLUE CROSS LABORATORIES LTD.	India	2.4	2.3	2.5	2.4	2.2	2.4	2.3	0.1	4.6	Pass	
129	B-005	B-005/MM14/YG/	OCID	Cadila Health Limited	India	6.0	3.6	3.6	3.9	5.8	4.1	4.5	1.1	24.6	Pass	
135	B-011	B-011/MM14/YG/	OCID	Cadila Health Limited	India	5.3	4.0	7.2	4.4	7.2	5.4	5.6	1.4	24.2	Pass	
194	B-070	B-070/MM14/YG/	OCID	Cadila Health Limited	India	3.7	3.9	3.8	2.5	3.1	2.5	3.3	0.6	19.7	Pass	
213	B-090	B-090/MM14/YG/	OCID	Cadila Health Limited	India	2.2	1.9	1.9	2.0	2.0	2.0	2.0	0.1	6.4	Pass	
3	PA-006	PA006/MM14/YG	OCID	Cadila Healthcare Limited	India	5.4	4.0	7.2	4.4	7.2	5.5	5.6	1.4	24.2	Pass	
5	A-002	A002/MM14/YG/	OCID	Cadila Healthcare Limited	India	3.0	2.7	2.6	2.6	2.5	4.0	2.9	0.6	19.1	Pass	
10	A-026	A026/MM14/YG/	OCID	Cadila Healthcare Limited	India	9.6	3.6	3.6	3.9	5.8	4.1	5.1	2.3	46.0	Pass	
16	A-042	A042/MM14/YG/	OCID	Cadila Healthcare Limited	India	5.6	5.0	3.6	3.8	5.0	5.4	4.7	0.8	17.2	Pass	
18	A-060	A060/MM14/YG/	OCID	Cadila Healthcare Limited	India	2.4	2.5	4.4	2.9	2.9	2.6	2.9	0.7	24.9	Pass	
25	A-084	A084/MM14/YG/	OCID	Cadila Healthcare Limited	India	9.9	9.5	7.3	9.6	9.7	10.0	9.3	1.0	10.8	Pass	
12	A-034	A034/MM14/YG/	LOMAC-20	Cipla Ltd.	India	26.9	27.7	27.7	27.3	28.1	23.5	26.9	1.7	6.3	Fail	Fail
13	A-038	A038/MM14/YG/	LOMAC-20	Cipla Ltd.	India	12.5	11.6	12.6	13.0	14.1	15.1	13.1	1.2	9.5	Fail	Fail
131	B-007	B-007/MM14/YG/	LOMAC	Cipla Ltd.	India	39.9	38.1	42.5	40.3	39.5	42.3	40.4	1.7	4.2	Fail	Fail
233	B-110	B110/MM14/YG/	LOMAC	Cipla Ltd.	India	24.4	25.4	25.1	24.7	25.4	21.1	24.4	1.7	6.8	Fail	Fail
124	PB-003	PB-003/MM14/YG	OMEZ	Dr. REDDY'S LABORATORIES	India	9.0	8.9	8.9	5.7	3.4	5.1	6.8	2.4	35.4	Pass	
130	B-006	B-006/MM14/YG/	OMEZ	Dr. REDDY'S LABORATORIES	India	5.8	2.9	5.3	9.1	8.8	8.7	6.8	2.5	37.1	Pass	
132	B-008	B-008/MM14/YG/	OMEZ	Dr. REDDY'S LABORATORIES	India	14.4	13.3	14.5	14.4	8.4	11.0	12.7	2.5	19.6	Fail	Fail
137	B-013	B-013/MM14/YG/	OMEZ	Dr. REDDY'S LABORATORIES	India	16.5	15.9	8.5	15.0	10.6	15.9	13.7	3.4	24.4	Fail	Fail
160	B-036	B-036/MM14/YG/	OMEZ	Dr. REDDY'S LABORATORIES	India	8.8	7.6	1.0	1.2	0.9	8.0	4.6	3.9	85.4	Pass	
178	B-054	B-054/MM14/YG/	OMEZ	Dr. REDDY'S LABORATORIES	India	22.8	26.4	28.2	24.0	25.3	27.4	25.7	2.1	8.0	Fail	Fail
229	B-106	B106/MM14/YG/	OMEZ	Dr. REDDY'S LABORATORIES	India	12.4	7.6	14.8	20.7	19.3	20.7	15.9	5.3	33.1	Fail	Fail
2	PA-005	PA005/MM14/YG	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	26.9	9.3	15.9	26.6	9.3	15.7	17.3	7.9	45.6	Fail	Fail
4	A-001	A001/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.8	5.9	7.5	9.3	6.9	7.4	7.8	1.5	19.1	Pass	
8	A-015	A015/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	14.3	9.3	16.8	15.2	15.9	9.7	13.5	3.2	23.9	Fail	Fail
14	A-039	A039/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.5	8.5	14.7	14.6	13.1	14.5	12.5	2.8	22.1	Fail	Fail
17	A-050	A050/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	10.5	9.2	20.2	17.3	17.9	24.3	16.6	5.8	34.9	Fail	Fail
19	A-061	A061/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.9	9.5	9.5	9.1	9.9	9.9	9.6	0.3	3.5	Pass	
20	A-065	A065/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.2	9.2	9.1	9.8	7.0	7.4	8.6	1.1	13.3	Pass	
29	A-101	A101/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	8.9	12.5	9.4	14.3	11.1	14.1	11.7	2.3	19.8	Fail	Pass
30	A-106	A106/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	1.9	1.9	1.9	1.9	1.9	1.9	1.9	0.0	0.0	Pass	
31	A-107	A107/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	4.8	4.7	4.6	4.5	4.6	4.4	4.6	0.1	3.3	Pass	
33	A-114	A114/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	1.9	1.9	1.9	1.9	1.9	1.9	1.9	0.0	0.0	Pass	
7	A-012	A012/MM14/YG/	Zosec	Emcure PHARMACETICALS LTD.	India	7.2	5.7	5.0	7.1	5.8	5.0	6.0	1.0	16.2	Pass	
141	B-017	B-017/MM14/YG/	Zosec	Emcure PHARMACEUTICAL LTD.	India	2.6	2.4	1.8	1.3	1.2	1.0	1.7	0.6	37.4	Pass	
161	B-037	B-037/MM14/YG/	OMFIL	Fourrts Laboratories Pvt Ltd,	India	3.5	7.1	5.1	4.2	6.8	5.0	5.3	1.4	26.7	Pass	
11	A-033	A033/MM14/YG/	OMFIL 20	Fourrts Laboratories Pvt.Ltd.	India	8.3	8.4	8.3	8.6	8.9	8.7	8.5	0.3	3.0	Pass	
169	B-045	B-045/MM14/YG/	OMPREZ	Global Pharma Healthcare Pvt, L	India	2.6	3.0	4.4	2.5	2.8	4.4	3.3	0.9	26.6	Pass	
15	A-041	A041/MM14/YG/	TRISEC	GREAT HIMALAYAN PTE LTD.	India	12.0	25.0	11.5	11.8	24.9	11.6	16.1	6.8	42.4	Fail	Fail
201	B-077	B-077/MM14/YG/	Ometab	Intas Pharmaceutical Ltd.	India	1.4	1.4	1.4	1.4	1.4	1.4	1.4	0.0	0.0	Pass	
231	B-108	B108/MM14/YG/	Ometab	Intas Pharmaceutical Ltd.	India	3.5	7.2	4.9	4.2	6.9	4.9	5.3	1.5	28.3	Pass	
123	PB-002	PB-002/MM14/YG	Ome-M	Rainbow Life Sciences Pvt. Ltd.	India	11.0	18.1	11.0	17.7	18.2	11.2	14.5	3.8	26.1	Fail	Fail
24	A-078	A078/MM14/YG/	Reloc-20	Rhydburg Pharmaceuticals Ltd.	India	23.0	34.4	17.1	23.3	33.1	16.6	24.6	7.6	31.1	Fail	Fail
6	A-011	A011/MM14/YG/	Omesec	The United Drug (1996) Co,Ltd.	Thailand	2.7	2.6	3.1	2.7	2.9	3.0	2.8	0.2	7.0	Pass	
26	A-091	A091/MM14/YG/	Omesec	The United Drug (1996) Co,Ltd.	Thailand	2.7	3.2	4.7	4.7	2.8	3.3	3.6	0.9	24.7	Pass	
183	B-059	B-059/MM14/YG/	Omesec	The United Drug(1996) Co., Ltd	Thailand	2.3	2.2	2.7	2.3	2.5	2.6	2.4	0.2	8.2	Pass	
28	A-097	A097/MM14/YG/	Omesafe	UNIVERSAL PHARMACEUTICALS LI	India	2.8	2.7	6.7	2.6	2.7	3.6	3.5	1.6	46.1	Pass	
173	B-049	B-049/MM14/YG/	Virom	Virchow Healthcare Drivate Limi	India	2.3	2.5	2.7	0.9	0.9	0.9	1.7	0.9	54.1	Pass	
139	B-015	B-015/MM14/YG/	HYCID	XL LABORATORIES PVT. LTD.	India	17.9	17.2	17.7	18.0	17.5	17.7	17.7	0.3	1.7	Fail	Fail
22	A-067	A067/MM14/YG/	HYCID	XL LABORATORIES PVT.LTD.	India	3.3	9.0	9.0	8.0	5.1	9.1	7.3	2.5	33.8	Pass	

Dissolution test BP: Buffer Stage

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	Disso Final Initial Judge	Disso Final New Judge Q=65*0.8+5%=57	Disso New Final Judge
51.3	79.2	76.0	65.2	77.9	70.0	70.0	10.5	15.1	Fail	Fail	Pass	Fail
56.0	52.7	47.6	56.4	54.1	48.6	52.6	3.7	7.1	Fail	Fail	Fail	Fail
82.7	94.3	95.4	96.0	95.4	96.1	93.3	5.2	5.6	Pass	Pass		
92.8	95.2	98.8	97.5	97.3	94.7	96.0	2.2	2.3	Pass	Pass		
81.6	92.7	89.7	83.0	93.3	91.8	88.7	5.1	5.8	Pass	Pass		
96.0	92.6	95.2	91.6	94.0	95.8	94.2	1.8	1.9	Pass	Pass		
96.6	97.9	98.3	66.4	98.5	97.3	92.5	12.8	13.9	Pass	Pass		
82.7	94.3	93.5	94.2	95.4	95.7	92.7	4.9	5.3	Pass	Pass		
77.0	79.8	80.1	81.4	80.1	77.2	79.3	1.8	2.2	Pass	Pass		
83.1	84.9	82.2	82.7	83.6	82.1	83.1	1.0	1.2	Pass	pass		
96.9	99.5	98.2	96.1	96.4	98.4	97.6	1.3	1.4	Pass	pass		
86.9	72.9	75.2	76.9	75.4	86.8	79.0	6.2	7.9	Pass	Pass		
97.9	95.6	97.7	95.1	96.2	95.7	96.4	1.2	1.2	Pass	Pass		
99.3	98.1	98.6	95.4	99.0	98.0	98.1	1.4	1.4	Pass	Pass		
77.0	79.8	80.1	94.3	94.4	95.4	86.8	8.7	10.0	Pass	Pass		
52.1	53.8	47.6	51.8	50.9	48.5	50.8	2.3	4.6	Fail	Fail	Fail	Fail
85.4	84.1	83.3	81.7	85.2	83.6	83.9	1.3	1.6	Pass	Fail		Fail
49.5	49.7	63.4	55.7	50.7	50.7	53.3	5.5	10.2	Fail	Fail	Fail	Fail
53.6	62.8	62.1	52.8	53.4	62.6	57.9	5.1	8.8	Fail	Fail	Pass	Fail
30.7	34.4	26.5	54.9	71.2	57.6	45.9	17.9	39.0	Fail	Fail	Fail	Fail
54.7	72.7	57.1	31.1	34.2	27.9	46.3	17.9	38.7	Fail	Fail	Fail	Fail
70.3	67.7	73.1	72.3	77.4	74.8	72.6	3.4	4.7	Fail	Fail	Pass	Fail
50.2	47.5	80.7	58.6	68.2	56.9	60.4	12.3	20.4	Fail	Fail	Pass	Fail
78.3	70.7	78.4	69.3	68.3	66.6	71.9	5.1	7.1	Fail	Fail	Pass	Fail
31.4	32.1	35.5	31.8	73.9	73.2	46.3	21.2	45.7	Fail	Fail	Fail	Fail
49.7	47.1	79.3	48.8	77.9	77.0	63.3	16.2	25.6	Fail	Fail	Pass	Fail
60.1	65.2	61.7	60.1	65.1	61.7	62.3	2.3	3.7	Fail	Fail	Pass	Fail
73.8	79.3	71.4	72.4	71.1	70.8	73.1	3.9	5.4	Pass	pass		
56.6	70.7	55.2	54.5	48.1	74.7	60.0	10.4	17.3	Fail	Fail	Pass	Fail
73.9	77.7	62.1	75.0	60.7	60.8	68.4	8.0	11.6	Fail	Fail	Pass	Fail
75.3	75.8	60.7	73.7	63.2	74.1	70.5	6.7	9.5	Fail	Fail	Pass	Fail
76.8	68.0	70.6	76.9	71.1	76.5	73.3	3.9	5.3	Fail	Fail	Pass	Pass
72.5	72.1	67.3	67.6	73.4	72.5	70.9	2.7	3.8	Fail	Fail	Pass	Pass
77.6	69.5	77.7	55.7	66.9	53.7	66.9	10.4	15.5	Fail	Fail	Pass	Pass
69.0	73.1	66.6	71.7	67.5	72.5	70.1	2.8	3.9	Fail	Fail	Pass	Pass
18.3	19.5	17.9	18.5	18.9	18.3	18.6	0.6	3.0	Fail	Fail	Fail	Fail
69.4	67.9	75.2	67.4	67.6	72.5	70.0	3.2	4.5	Fail	Fail	Pass	Pass
80.0	74.7	91.1	80.0	76.4	90.3	82.1	7.0	8.5	Pass	pass		
99.6	98.6	98.8	97.7	97.4	94.6	97.8	1.8	1.8	Pass	Pass		
92.2	86.9	87.1	91.1	88.9	92.9	89.9	2.6	2.9	Pass	Pass		
67.6	81.2	79.8	80.6	68.5	68.2	74.3	6.8	9.2	Fail	Fail	Pass	Pass
71.7	94.3	86.6	73.1	93.9	86.8	84.4	9.9	11.7	Pass	Pass		
59.7	98.8	61.0	59.7	98.7	61.4	73.2	19.8	27.1	Fail	Fail	Pass	Fail
87.1	86.9	87.2	86.4	88.0	87.9	87.2	0.6	0.7	Pass	Pass		
92.2	87.5	87.3	91.2	88.4	92.3	89.8	2.3	2.6	Pass	Pass		
51.5	60.6	59.9	50.7	51.3	60.4	55.7	5.0	9.0	Fail	Fail	Fail	Fail
49.4	43.5	50.8	49.9	44.1	50.9	48.1	3.4	7.1	Fail	Fail	Fail	Fail
93.5	91.0	92.9	89.3	92.8	94.3	92.3	1.8	2.0	Pass	pass		
89.9	93.5	95.8	99.9	95.9	98.2	95.5	3.5	3.7	Pass	Pass		
93.9	97.7	99.8	93.3	93.4	91.2	94.9	3.2	3.4	Pass	Pass		
94.6	95.2	78.9	96.5	80.6	82.9	88.1	8.1	9.2	Pass	Pass		
66.4	85.3	84.9	65.6	83.7	66.3	75.4	10.2	13.5	Fail	Fail	Pass	Fail
39.7	38.5	42.8	39.8	38.9	42.6	40.4	1.9	4.6	Fail	Fail	Fail	Fail
82.2	71.8	73.5	86.2	70.2	76.3	76.7	6.3	8.2	Pass	Pass		

2nd Stage-Acid Stage

% of Quantity Capsule 1	% of Quantity capsule 2	% of Quantity Capsule 3	% of Quantity capsule 4	% of Quantity Capsule 5	% of Quantity capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	New Judge 10% *1.2= 12% dissolved
10.2	8.7	3.0	8.9	8.7	10.5	10.3	4.4	42.4	Pass	
7.8	8.3	6.8	7.7	6.8	9.5	9.4	1.8	19.4	Pass	
33.7	31.6	34.5	34.8	35.5	39.3	24.0	11.5	47.9	Fail	Fail
25.0	25.8	22.1	26.5	27.9	32.4	25.5	2.8	11.1	Fail	Fail
7.0	6.5	8.8	4.3	6.9	8.4	9.8	3.6	36.4	Pass	
3.8	6.8	3.9	5.1	3.6	4.6	9.2	5.3	58.0	Pass	
8.8	10.7	9.1	10.0	8.2	12.8	7.3	4.0	55.2	Pass	
12.0	16.3	11.1	12.1	14.2	11.2	14.4	4.1	28.8	Fail	Fail
4.4	3.9	4.0	5.7	18.3	6.8	10.4	5.4	52.6	Pass	
1.3	5.6	6.8	4.1	4.5	3.8	8.4	4.8	57.0	Pass	
3.7	4.3	6.6	3.8	3.3	5.1	10.5	7.5	71.0	Fail	Pass
15.6	11.1	11.7	13.1	11.7	12.7	14.4	5.1	35.2	Fail	Fail
11.6	3.0	13.5	12.7	11.0	12.3	12.6	4.2	33.0	Fail	Fail
8.0	7.5	6.8	6.7	6.4	7.8	4.4	3.0	67.2	Pass	

2nd Stage-Buffer

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Initial Judge	Disso Initial Final Judge	New Judge Q=52	Disso New Final Judge
63.5	71.2	102.5	64.7	76.4	46.9	70.4	14.3	20.3	Pass	Pass		
71.2	64.9	74.5	64.9	73.3	61.8	60.5	9.4	15.5	Fail	Fail	Pass	Pass
37.1	49.6	41.5	37.8	49.6	40.3	63.2	21.9	34.6	Fail	Fail	Pass	Fail
35.2	34.1	32.5	34.1	35.7	37.1	46.3	12.6	27.2	Fail	Fail	Fail	Fail
63.3	52.7	60.6	51.7	42.5	50.0	63.0	11.4	18.2	Fail	Fail	Pass	Pass
65.6	54.7	62.1	63.1	63.3	64.9	61.3	8.8	14.3	Fail	Fail	Pass	Pass
74.9	64.9	61.2	65.5	62.3	75.3	69.6	5.9	8.5	Pass	Pass		
34.0	27.7	31.1	32.4	28.6	26.2	46.6	20.7	44.3	Fail	Fail	Fail	Fail
58.8	81.4	72.6	67.6	73.9	64.5	64.9	10.2	15.7	Pass	Pass		
80.5	74.6	75.1	60.4	64.0	67.9	69.4	7.5	10.8	Pass	Pass		
67.2	52.1	62.3	79.2	65.7	76.5	68.8	8.2	12.0	Pass	Fail		Pass
38.4	71.2	56.3	41.9	38.2	69.0	62.9	15.2	24.1	Fail	Fail	Pass	Pass
60.6	41.1	48.6	52.5	64.5	50.4	61.9	11.1	18.0	Fail	Fail	Pass	Pass
69.8	61.6	66.0	53.7	60.9	68.5	65.1	8.3	12.7	Pass	Pass		
39.2	67.8	56.7	43.5	41.6	69.6	61.6	12.9	20.9	Fail	Fail	Pass	Pass
53.0	69.8	66.7	60.4	61.1	66.8	66.5	5.9	8.9	Pass	Pass		
61.7	78.7	77.4	71.1	81.4	81.0	74.8	6.9	9.2	Pass	Pass		
24.3	18.1	29.6	19.4	22.9	18.6	47.7	30.0	62.9	Fail	Fail	Fail	Fail
61.8	90.6	60.5	64.9	57.5	53.4	60.2	10.7	17.7	Fail	Fail	Pass	Fail
65.6	72.1	81.4	78.6	78.2	80.4	75.7	8.0	10.5	Pass	Pass		

Content uniformity test BP (1st stage)

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	% of Quantity Capsule 7	% of Quantity Capsule 8	% of Quantity Capsule 9	% of Quantity Capsule 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge	New Judge AV=18	Mean % of Quantity	Judge	New Judge BP 76.0≦mean≦126
98.4	103.4	96.8	103.9	100.1	99.0	94.2	99.7	98.1	95.7	98.9	3.1	3.1	7.4	Pass		98.9	Pass	
90.5	91.9	91.6	95.1	95.2	96.6	91.0	90.8	91.1	96.5	93.0	2.5	2.7	11.5	Pass		93.0	Fail	Pass
88.2	87.8	86.7	97.1	83.7	84.2	88.3	93.3	85.2	105.7	90.0	6.9	7.6	25.0	Fail	Fail	90.0	Fail	Pass
99.9	103.1	98.4	102.9	105.9	94.3	102.8	101.5	98.1	103.8	101.1	3.4	3.4	8.2	Pass		101.1	Pass	
97.5	95.4	81.2	90.8	100.2	98.4	100.1	94.5	93.9	101.2	95.3	6.0	6.2	17.5	Fail	Pass	95.3	Pass	
99.1	108.0	100.1	99.8	99.6	106.5	103.0	100.4	104.1	107.9	102.9	3.6	3.5	7.2	Pass		102.9	Pass	
102.7	102.6	105.7	101.5	96.8	106.0	106.1	105.5	101.0	106.7	103.5	3.1	3.0	5.6	Pass		103.5	Pass	
95.9	94.0	97.5	91.8	91.4	90.8	99.0	100.9	96.1	104.8	96.2	4.5	4.7	13.0	Pass		96.2	Pass	
97.1	94.1	95.2	100.0	99.5	100.9	92.6	105.0	97.8	102.7	98.5	3.9	4.0	9.4	Pass		98.5	Pass	
107.7	105.9	104.9	101.8	99.9	104.6	103.2	104.3	107.8	105.1	104.5	2.4	2.3	2.8	Pass		104.5	Pass	
101.6	106.5	107.0	106.7	106.5	105.2	106.5	104.5	109.7	109.8	106.4	2.4	2.2	0.8	Pass		106.4	Fail	Pass
101.4	106.5	106.8	106.7	106.5	105.1	107.9	107.4	109.2	109.7	106.7	2.3	2.2	0.3	Pass		106.7	Fail	Pass
99.5	107.6	104.4	106.9	104.4	109.8	107.9	109.4	108.3	105.4	106.4	3.1	2.9	2.5	Pass		106.4	Fail	Pass
99.6	108.0	99.8	98.9	106.3	105.3	104.0	99.5	100.2	102.9	102.4	3.3	3.2	7.0	Pass		102.4	Pass	
99.8	107.9	104.5	107.2	104.5	109.8	107.8	109.6	108.4	105.8	106.5	3.0	2.8	2.2	Pass		106.5	Fail	Pass
91.1	91.6	92.7	97.9	99.0	97.1	94.9	96.7	93.7	93.8	94.9	2.7	2.9	10.2	Pass		94.9	Pass	
89.8	92.1	89.0	88.8	90.8	93.0	92.2	93.5	90.0	84.7	90.4	2.6	2.9	14.3	Pass		90.4	Fail	Pass
89.8	92.1	89.1	88.9	91.0	93.0	92.3	93.5	89.9	84.8	90.4	2.6	2.9	14.2	Pass		90.4	Fail	Pass
87.9	89.2	89.3	87.9	90.6	87.9	88.6	85.5	91.0	93.8	89.2	2.2	2.5	5.4	Pass		89.2	Fail	Pass
92.1	96.0	90.3	91.2	92.0	95.0	94.2	93.6	95.9	96.5	93.7	2.2	2.3	10.1	Pass		93.7	Fail	Pass
96.4	94.7	95.8	91.6	97.6	92.5	97.6	96.6	98.5	98.0	95.9	2.3	2.4	8.2	Pass		95.9	Pass	
102.0	95.8	110.0	107.2	107.8	108.5	106.7	98.2	105.6	105.3	104.7	4.6	4.4	7.9	Pass		104.7	Pass	
90.7	95.5	93.6	91.0	99.3	90.8	96.0	91.3	98.0	91.7	93.8	3.2	3.4	12.4	Pass		93.8	Fail	Pass
96.2	97.8	99.7	95.8	98.9	94.6	93.0	93.6	98.6	90.6	95.9	2.9	3.1	9.7	Pass		95.9	Pass	
93.5	94.2	102.0	93.3	96.1	93.1	98.5	100.9	92.9	93.8	95.8	3.4	3.6	10.9	Pass		95.8	Pass	
98.9	93.0	95.9	96.4	100.3	99.5	92.0	96.3	100.5	103.6	97.6	3.6	3.7	9.5	Pass		97.6	Pass	
96.3	101.6	92.5	98.5	99.4	96.6	97.9	96.6	100.0	98.2	97.8	2.5	2.5	6.7	Pass		97.8	Pass	
101.2	94.0	105.6	98.6	101.9	98.5	95.0	95.6	102.6	102.7	99.6	3.8	3.9	8.2	Pass		99.6	Pass	
90.0	90.9	92.3	92.2	95.9	95.4	92.5	94.4	93.4	92.2	92.9	1.9	2.0	10.1	Pass		92.9	Fail	Pass
93.2	98.1	96.6	99.7	95.5	94.3	97.0	97.2	96.9	101.7	97.0	2.5	2.5	7.4	Pass		97.0	Pass	
90.1	95.5	92.5	95.0	96.7	103.7	98.3	90.8	95.4	97.0	95.5	3.9	4.1	12.4	Pass		95.5	Pass	
92.1	102.4	99.3	96.7	92.8	98.1	95.1	100.4	98.0	98.5	97.3	3.3	3.4	9.0	Pass		97.3	Pass	
92.3	94.7	98.9	100.1	99.6	95.7	93.9	95.3	92.7	97.2	96.0	2.8	2.9	9.1	Pass		96.0	Pass	
95.2	90.3	96.8	103.7	95.0	92.6	98.2	90.7	95.9	97.1	95.5	3.9	4.1	12.4	Pass		95.5	Pass	
92.5	92.6	96.1	92.2	92.3	90.0	91.1	93.6	94.5	95.4	93.0	1.9	2.0	10.0	Pass		93.0	Fail	Pass
94.8	92.6	97.8	98.2	97.0	92.0	98.3	96.7	99.3	96.0	96.3	2.5	2.6	8.2	Pass		96.3	Pass	
97.1	93.7	96.7	97.7	94.0	93.4	94.0	96.9	91.6	93.9	94.9	2.0	2.1	8.5	Pass		94.9	Pass	
56.5	47.1	95.7	99.2	77.9	47.6	83.0	72.5	85.2	99.6	76.4	20.1	26.4	70.4	Fail	Fail	76.4	Fail	Pass
89.0	91.5	96.7	95.8	98.8	100.1	88.1	90.3	93.3	92.7	93.6	4.1	4.4	14.7	Pass		93.6	Fail	Pass
92.4	93.0	94.0	99.5	100.6	98.6	96.3	98.2	94.8	95.2	96.3	2.8	3.0	9.1	Pass		96.3	Pass	
75.6	84.7	81.9	86.5	101.0	80.1	99.1	100.1	95.9	91.3	89.6	9.1	10.2	30.8	Fail	Fail	89.6	Fail	Pass
93.0	78.3	77.4	76.2	89.1	94.1	91.4	97.8	82.9	87.6	86.8	7.7	8.8	30.1	Fail	Fail	86.8	Fail	Pass
109.2	107.2	107.9	106.3	102.1	105.1	104.5	105.3	106.4	100.3	105.4	2.7	2.5	2.4	Pass		105.4	Pass	
86.1	91.8	87.7	83.8	90.4	86.5	88.2	89.4	84.2	90.7	87.9	2.7	3.1	17.2	Fail	Pass	87.9	Fail	Pass
101.2	101.4	98.2	99.3	96.9	96.9	98.6	96.0	99.1	101.5	98.9	2.0	2.0	4.7	Pass		98.9	Pass	
90.9	81.7	99.9	92.7	93.5	85.0	85.6	87.3	85.5	86.5	88.8	5.4	6.0	22.5	Fail	Fail	88.8	Fail	Pass
99.8	94.0	62.2	62.5	76.6	45.5	73.8	90.3	76.0	78.7	75.9	16.4	21.5	61.8	Fail	Fail	75.9	Fail	Fail
100.0	93.9	99.7	95.4	96.7	97.9	98.4	98.9	104.0	103.3	98.8	3.2	3.2	7.6	Pass		98.8	Pass	
93.3	94.5	96.5	91.2	96.4	95.7	93.8	92.6	98.3	98.7	95.1	2.4	2.6	9.3	Pass		95.1	Pass	
98.3	90.0	97.8	90.3	99.0	101.3	101.6	104.2	103.4	103.3	98.9	5.1	5.2	12.2	Pass		98.9	Pass	
94.1	103.4	99.3	101.9	96.4	104.2	97.3	103.5	98.6	104.0	100.3	3.6	3.6	8.7	Pass		100.3	Pass	
80.6	69.2	77.8	80.0	89.5	78.4	85.0	85.6	82.6	83.4	81.2	5.5	6.8	30.5	Fail	Fail	81.2	Fail	Pass
98.6	113.1	90.3	98.3	116.2	96.6	100.7	108.9	113.3	113.5	104.9	9.1	8.6	18.3	Fail	Fail	104.9	Pass	
88.1	99.5	100.1	94.7	95.0	89.9	98.0	87.3	90.8	91.6	93.5	4.7	5.0	16.2	Fail	Pass	93.5	Fail	Pass

Content uniformity test BP (2nd stage)

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	% of Quantity Capsule 7	% of Quantity Capsule 8	% of Quantity Capsule 9	% of Quantity Capsule 10	% of Quantity Capsule 11	% of Quantity Capsule 12	% of Quantity Capsule 13	% of Quantity Capsule 14	% of Quantity Capsule 15	% of Quantity Capsule 16	% of Quantity Capsule 17	% of Quantity Capsule 18	% of Quantity Capsule 19	% of Quantity Capsule 20	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	M value for AV	AV (Acceptance Value)	Judge	New Judge AV= 18
																								7.4	Pass	
																								11.5	Pass	
88.9	85.0	89.7	87.8	102.7	97.3	98.9	109.5	97.1	90.5	92.6	92.9	88.6	95.2	98.7	108.9	96.7	81.7	95.7	95.7	93.2	7.3	7.8	98.5	19.9	Fail	Fail
																								8.2	Pass	
																								17.5	Pass	
																								7.2	Pass	
																								5.6	Pass	
																								13.0	Pass	
																								9.4	Pass	
																								2.8	Pass	
																								0.8	Pass	
																								0.3	Pass	
																								2.5	Pass	
																								7.0	Pass	
																								2.2	Pass	
																								10.2	Pass	
																								14.3	Pass	
																								14.2	Pass	
																								5.4	Pass	
																								10.1	Pass	
																								8.2	Pass	
																								7.9	Pass	
																								12.4	Pass	
																								9.7	Pass	
																								10.9	Pass	
																								9.5	Pass	
																								6.7	Pass	
																								8.2	Pass	
																								10.1	Pass	
																								7.4	Pass	
																								12.4	Pass	
																								9.0	Pass	
																								9.1	Pass	
																								12.4	Pass	
																								10.0	Pass	
																								8.2	Pass	
																								8.5	Pass	
																								70.4	Fail	Fail
																								14.7	Pass	
																								9.1	Pass	
109.2	95.3	93.1	91.4	97.5	98.6	109.9	98.7	94.3	89.2	92.7	103.1	95.8	90.7	90.1	88.0	99.3	88.9	85.3	96.8	93.5	7.9	8.4	98.5	20.8	Fail	Fail
79.9	91.1	90.9	95.6	95.4	104.3	102.6	104.3	87.3	91.6	91.8	93.4	96.9	89.8	93.8	94.0	85.5	95.2	95.5	97.6	91.5	7.3	7.9	98.5	21.6	Fail	Fail
																								2.4	Pass	
90.0	90.2	87.1	93.9	90.6	92.2	92.3	94.5	92.4	93.0	93.9	94.0	90.7	95.6	91.5	94.3	92.0	93.7	92.7	93.5	90.9	3.1	3.4	98.5	13.8	Pass	
																								4.7	Pass	
98.8	102.9	93.9	89.2	88.4	92.5	93.6	100.4	90.5	96.6	102.7	94.0	95.9	100.6	98.1	92.9	104.4	92.8	96.9	100.1	93.8	6.0	6.4	98.5	16.7	Fail	Pass
																								61.8	Fail	Fail
																								7.6	Pass	
																								9.3	Pass	
																								12.2	Pass	
																								8.7	Pass	
																								30.5	Fail	Fail
106.1	96.1	109.7	111.1	98.0	101.1	106.5	92.3	97.5	108.2	107.4	108.5	108.7	107.6	107.5	98.5	110.9	99.6	108.6	107.2	104.7	6.8	6.5	101.5	10.4	Pass	
90.3	96.0	102.0	98.0	101.1	93.0	92.4	101.6	104.0	95.1	98.0	103.5	93.5	96.2	97.9	87.3	88.3	92.0	97.4	87.7	95.0	5.0	5.3	98.5	13.6	Pass	

Comparisons the results BP in QTY, DS and all test

Kanazawa Univ. Quantity test (10 caps)	Judge	New Judge	DS Final Judge	DS New Final Judge	All test pass or any fail	New All test pass or any fail
98.9	Pass		Pass		Pass	
93.0	Fail	Pass	Fail	Pass	Fail	Fail
90.0	Fail	Pass	Pass		Fail	Fail
101.1	Pass		Pass		Pass	
95.3	Pass		Pass		Pass	
102.9	Pass		Pass		Pass	
103.5	Pass		Pass		Pass	
96.2	Pass		Pass		Pass	
98.5	Pass		Pass		Pass	
104.5	Pass		Pass		Pass	
106.4	Fail	Pass	Pass		Fail	Pass
106.7	Fail	Pass	Pass		Fail	Pass
106.4	Fail	Pass	Pass		Fail	Pass
102.4	Pass		Pass		Pass	
106.5	Fail	Pass	Pass		Fail	Pass
94.9	Pass		Fail	Fail	Fail	Fail
90.4	Fail	Pass	Fail	Fail	Fail	Fail
90.4	Fail	Pass	Fail	Fail	Fail	Fail
89.2	Fail	Pass	Fail	Fail	Fail	Fail
93.7	Fail	Pass	Fail	Fail	Fail	Fail
95.9	Pass		Fail	Fail	Fail	Fail
104.7	Pass		Pass		Pass	
93.8	Fail	Pass	Pass		Fail	Pass
95.9	Pass		Pass		Pass	
95.8	Pass		Fail	Fail	Fail	Fail
97.6	Pass		Fail	Fail	Fail	Fail
97.8	Pass		Fail	Fail	Fail	Fail
99.6	Pass		Pass		Pass	
92.9	Fail	Pass	Pass		Fail	Pass
97.0	Pass		Pass		Pass	
95.5	Pass		Pass		Pass	
97.3	Pass		Fail	Pass	Fail	Pass
96.0	Pass		Pass		Pass	
95.5	Pass		Pass		Pass	
93.0	Fail	Pass	Fail	Pass	Fail	Pass
96.3	Pass		Fail	Fail	Fail	Fail
94.9	Pass		Pass		Pass	
76.4	Fail	Pass	Pass		Fail	Pass
93.6	Fail	Pass	Pass		Fail	Pass
96.3	Pass		Pass		Pass	
89.6	Fail	Pass	Pass		Fail	Fail
86.8	Fail	Pass	Pass		Fail	Fail
105.4	Pass		Fail	Fail	Fail	Fail
87.9	Fail	Pass	Pass		Fail	Pass
98.9	Pass		Pass		Pass	
88.8	Fail	Pass	Fail	Fail	Fail	Fail
75.9	Fail	Fail	Fail	Fail	Fail	Fail
98.8	Pass		Pass		Pass	
95.1	Pass		Pass		Pass	
98.9	Pass		Pass		Pass	
100.3	Pass		Pass		Pass	
81.2	Fail	Pass	Pass		Fail	Fail
104.9	Pass		Fail	Fail	Fail	Fail
93.5	Fail	Pass	Pass		Fail	Pass

Dissolution test USP: 1st stage Acid Resistance Stage

Serial No.	Sample Code	Trade name of the	Name of Manufacturer	Manufactt	% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	New Judge 10% *1.2= 12% dissolved
B-016	B-016/MM14/YG	Sumicef	AMN Life Sience Pvt Ltd.,	India	10.9	10.8	4.0	2.8	8.9	6.9	7.4	3.5	46.8	Pass	
B-043	B-043/MM14/YG	Sumicef	AMN Life Sience Pvt Ltd.,	India	5.8	8.3	4.0	1.6	14.0	4.4	6.3	4.3	68.4	Pass	
A-021	A021/MM14/YG/	OMAPIN-20	BRAWN LABORATORIES LTD.	India	2.0	4.6	3.7	0.5	2.9	4.5	3.0	1.6	52.7	Pass	
B-012	B-012/MM14/YG	OMAPIN	BRAWN LABORATORIES LTD.	India	4.3	8.4	6.1	9.8	7.9	8.0	7.4	2.0	26.3	Pass	
B-074	B-074/MM14/YG	OMEPRAZOLE	GOLDEN KABAW PTE. LTD	Singapor	14.3	11.3	14.3	10.7	14.1	14.4	13.2	1.7	12.9	Pass	
B-046	B-046/MM14/YG	OMAC	MDC PHARMACEUTICALS (P)Ltd	India	0.8	1.8	1.6	5.8	4.5	6.9	3.6	2.5	70.0	Pass	
B-071	B-071/MM14/YG	OMAC	MDC PHARMACEUTICALS (P)Ltd	India	0.6	12.5	6.3	10.1	4.8	2.2	6.1	4.6	75.1	Pass	
B-078	B-078/MM14/YG	OMAC	MDC PHARMACEUTICALS (P)Ltd	India	1.2	1.3	3.4	2.7	1.4	13.5	3.9	4.8	122.3	Pass	
PA-004	PA004/MM14/YG	OMAC	MDC PHARMACEUTICALS(P) LTD.	India	12.6	11.2	12.6	12.8	13.2	11.4	12.3	0.8	6.7	Pass	
A-066	A066/MM14/YG/	OMAC	MDC PHARMACEUTICALS(P) LTD.	India	11.7	5.3	1.8	12.2	11.3	9.8	8.7	4.2	48.5	Pass	
A-113	A113/MM14/YG/	OMAC	MDC PHARMACEUTICALS(P) LTD.	India	17.1	11.2	7.8	17.6	16.7	15.3	14.3	3.9	27.6	Fail	Fail

Dissolution test USP: Buffer 1st Stage

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	Disso Final Initial Judge	Disso Final New Judge Q=65*0.8+ 5%=57	Disso New Final Judge
89.4	87.9	90.5	92.6	92.2	89.5	90.3	1.8	2.0	Pass	Pass		
90.7	85.0	90.3	89.7	90.1	91.9	89.6	2.4	2.7	Pass	Pass		
86.1	95.4	95.7	96.3	88.0	93.2	92.4	4.3	4.7	Pass	Pass		
92.8	97.9	93.9	90.9	92.7	97.6	94.3	2.9	3.0	Pass	Pass		
77.1	81.7	80.0	78.6	81.4	77.7	79.4	1.9	2.4	Fail	Fail	Pass	Pass
83.4	89.1	86.9	88.0	85.5	88.4	86.9	2.1	2.5	Pass	Pass		
88.4	89.2	86.4	87.5	93.3	87.8	88.8	2.4	2.7	Pass	Pass		
85.6	89.2	86.5	87.5	90.0	87.6	87.7	1.6	1.9	Pass	Pass		
89.4	90.4	99.5	91.6	92.2	96.4	93.2	3.9	4.2	Pass	Pass		
88.8	89.9	98.9	91.0	91.7	95.9	92.7	3.9	4.2	Pass	Pass		
81.2	77.6	80.0	78.6	77.3	75.9	78.4	1.9	2.5	Fail	Fail	Pass	Fail

Content uniformity 1st considered range USP

106.7	105.7	103.3	107.9	105.9	97.6	104.6	94.6	103.2	104.0	103.4	4.1	4.0	8.1	Pass		103.4	Pass		
105.1	104.8	106.7	104.0	108.5	103.9	108.2	107.7	105.3	105.7	106.0	1.7	1.6	9.3	Pass		106.0	Pass		
93.7	98.7	97.3	93.1	102.3	101.1	92.4	93.3	90.7	107.7	97.0	5.4	5.6	14.4	Pass		97.0	Pass		
102.2	96.2	110.0	107.4	107.9	108.5	106.8	98.5	103.9	105.3	104.7	4.5	4.3	7.7	Pass		104.7	Pass		
88.9	63.0	70.3	62.4	86.7	84.7	70.0	70.9	95.3	91.9	78.4	12.3	15.7	49.7	Fail	Fail	78.4	Fail	Pass	
109.7	108.2	109.3	100.4	108.1	109.8	106.6	102.4	107.7	107.6	107.0	3.2	2.9	2.1	Pass		107.0	Pass		
98.0	92.7	99.3	100.4	105.5	90.2	96.2	101.2	101.2	93.3	97.8	4.7	4.8	11.9	Pass		97.8	Pass		
97.1	93.1	100.6	106.6	99.6	98.8	93.2	98.1	104.6	93.3	98.5	4.7	4.7	11.2	Pass		98.5	Pass		
90.1	104.8	101.3	101.7	97.1	108.1	100.5	102.6	99.5	103.5	100.9	4.8	4.8	11.6	Pass		100.9	Pass		
100.0	94.7	101.4	102.5	107.7	92.1	98.3	103.3	103.3	95.2	99.9	4.8	4.8	11.5	Pass		99.9	Pass		
93.4	106.4	98.1	93.7	103.5	94.4	91.0	95.3	94.7	105.6	97.6	5.5	5.7	14.2	Pass		97.6	Pass		

CTRX, USP sample with considered range

Serial N	Sample Code	Trade name of Name of Manuf	Manufactur	% of Quantity Vial1	% of Quantity Vial 2	% of Quantity Vial 3	% of Quantity Vial 4	% of Quantity Vial 5	% of Quantity Vial 6	% of Quantity Vial 7	% of Quantity Vial 8	% of Quantity Vial 9	% of Quantity Vial 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	QTY Judge	New QTY Judge	AV (Acceptance Value)	CU Judge	CU Judge	AV (Acceptance Value)	CU Judge	New OU Judge	Kanazawa Univ. Quantity test (10 Val	Judge	New Judge	New All Fail Judge
A-010	A010/NM14/YG/01/H BECEF	Nectar Lifesci India		124.43	122.277	117.405	111.121	122.58	119.109	115.877	111.927	119.555	112.343	117.7	4.7631335	4.0481356	Fail	Pass	27.63	Fail	Fail	27.63	Fail	Fail	117.66	Fail	Pass	Fail
A-028	A028/NM14/YG/04/G TEFAXONE	Stallion LABOI India		102.6	102.6	103.4	105.3	104.2	104.1	101.2	103.0	103.5	103.0	103.3	1.1204033	1.0847109	Pass		4.49	Pass		4.49	Pass		103.29	Pass		
A-047	A047/NM14/YG/05/G TRAXONE	Korea Pharma Korea		107.8	108.2	109.4	107.9	105.1	108.6	106.3	108.6	109.0	108.6	108.0	1.301357	1.2052888	Pass		9.62	Pass		9.62	Pass		107.97	Pass		
A-062	A062/NM14/YG/01/G LYFAXONE	LYKA LABS LIMI India		111.0	110.2	112.2	113.9	115.4	111.1	115.0	110.3	111.4	110.3	112.1	1.9964575	1.7812202	Pass		15.00	Pass		15.00	Pass		112.08	Pass		
A-087	A087/NM14/YG/01/W Ceftron	SQUARE PHARI Banglades		106.5	104.4	106.2	108.2	105.9	109.3	107.5	109.5	105.8	109.5	107.3	1.7882748	1.6670657	Pass		10.10	Pass		10.10	Pass		107.27	Pass		
A-093	A093/NM14/YG/03/W DALITRIXON	SHENZHEN Zhi China		107.8	108.6	108.8	108.2	110.6	110.6	110.3	105.4	109.5	105.4	108.5	1.9207722	1.7702399	Pass		11.61	Pass		11.61	Pass		108.50	Pass		
A-094	A094/NM14/YG/03/W TRAXEF	CCL Pharmaceu Pakistan		108.8	108.3	108.7	108.9	108.3	107.7	107.8	108.8	110.9	108.8	108.7	0.8792508	0.8088747	Pass		9.31	Pass		9.31	Pass		108.70	Pass		
B-014	B-014/NM14/YG/04/(C Tri	Emcure PHARN India		108.6	109.9	108.3	109.1	107.7	107.4	109.1	107.7	108.6	107.7	108.4	0.8211277	0.7574986	Pass		8.87	Pass		8.87	Pass		108.40	Pass		
B-020	B-020/NM14/YG/05/(UTRIXONE	UMEDICA LABC India		106.5	105.2	106.2	103.7	104.6	106.2	109.2	109.8	107.0	109.8	106.8	2.1423105	2.0056308	Pass		10.34	Pass		10.34	Pass		106.81	Pass		
B-041	B-041/NM14/YG/01/I POWERCEF	WOCKHARDT Li India		105.7	106.0	109.9	106.6	103.9	105.9	103.7	107.6	105.2	107.6	106.2	1.8691588	1.7599819	Pass		10.19	Pass		10.19	Pass		106.20	Pass		
B-082	B-082/NM14/YG/01/(ZEFONE	Cadila Health India		109.2	108.5	109.4	108.2	109.1	105.6	106.0	107.7	108.5	107.7	108.0	1.2988663	1.2027108	Pass		9.62	Pass		9.62	Pass		107.99	Pass		
PA-007	PA007/NM14/YG/01/(Oframax	RANBAXY LABC India		108.7	109.0	108.3	108.2	108.5	108.9	107.7	108.0	110.3	108.0	108.5	0.7328835	0.675193	Pass		8.75	Pass		8.75	Pass		108.54	Pass		
A-031	A031/NM14/YG/01/O PARCEF	Jayson Pharm Bangladesl		89.34	139.89	135.054	124.33	117.37	121.08	107.18	122.08	124.42	121.78	118.6	13.860013	11.685618	Fail	Pass	50.36	Fail	Fail	50.36	Fail	Fail	118.61	Fail	Pass	Fail
A-098	A098/NM14/YG/01/H CEFTRIAXON	M.I.BIOPHARM India		106.39	113.20	109.84	114.41	112.13	111.64	110.36	108.79	109.40	110.76	110.7	2.3030828	2.0806339	Pass		14.72	Pass		14.72	Pass		110.69	Pass		
B-021	B-021/NM14/YG/05/(CEFDEC	BELCO PHARM India		106.65	110.03	111.10	106.70	107.92	108.31	105.68	107.16	105.24	107.51	107.6	1.8231694	1.6939404	Pass		10.46	Pass		10.46	Pass		107.63	Pass		
B-025	B-025/NM14/YG/06/(Ceftriaxone	Wyanma Phari Myanmar		106.55	105.70	109.19	105.16	104.43	109.46	113.24	113.02	103.04	102.31	107.2	3.875495	3.6148768	Pass		15.00	Pass		15.00	Pass		107.21	Pass		
B-033	B-033/NM14/YG/01/I Rocephin	F.Hoffmann-La Switzland		111.40	109.24	112.44	111.26	110.71	114.94	111.58	115.00	109.41	109.91	111.6	2.0431297	1.8309534	Pass		15.00	Pass		15.00	Pass		111.59	Pass		
A-055	A055/NM14/YG/01/H Oframax	RANBAXY LABC India		114.68	103.49	104.38	103.70	104.15	104.08	103.53	105.26	107.14	105.26	105.6	3.3886221	3.2099285	Pass		12.23	Pass		12.23	Pass		105.57	Pass		
B-097	B-097/NM14/YG/02/(BECEF	Nectar Lifesci India		113.50	113.38	113.42	114.97	115.92	114.78	115.17	113.23	113.86	113.23	114.1	0.9770122	0.8559388	Pass		14.95	Pass		14.95	Pass		114.15	Pass		
A-027	A027/NM14/YG/04/Q BECEF	Nectar Lifesci India		106.35	109.31	104.98	102.93	105.69	108.25	106.14	108.87	104.40	104.51	106.1	2.0958745	1.9746004	Pass		9.64	Pass		9.64	Pass		106.14	Pass		
A-029	A029/NM14/YG/04/Q LYFAXONE	LYKA LABS LIMI India		108.98	108.90	107.80	101.91	102.47	109.30	105.43	107.81	105.95	101.11	105.5	3.0044357	2.8487271	Pass		11.10	Pass		11.10	Pass		105.47	Pass		
A-051	A051/NM14/YG/01/H Oframax	RANBAXY LABC India		111.91	105.87	104.91	104.09	105.81	105.61	103.08	110.40	107.50	108.68	106.8	2.8104251	2.6318637	Pass		12.53	Pass		12.53	Pass		106.78	Pass		
A-110	A110/NM14/YG/01/Q Trixone	TOQUIR Pharm India		104.25	97.81	101.04	99.92	106.75	101.00	103.82	101.96	105.13	103.37	102.5	2.6651732	2.6000647	Pass		7.41	Pass		7.41	Pass		102.50	Pass		
B-010	B-010/NM14/YG/02/(Cefaxone	LUPIN LTD. India		109.63	104.08	103.56	106.66	109.69	104.92	103.62	104.70	106.78	104.55	105.8	2.3035502	2.1768777	Pass		9.82	Pass		9.82	Pass		105.82	Pass		
A-008	A008/NM14/YG/01/H Oframax	RANBAXY LABC India		110.31	107.77	108.26	107.07	108.79	107.31	108.13	108.93	107.37	110.81	108.5	1.2629433	1.1642606	Pass		10.02	Pass		10.02	Pass		108.48	Pass		
A-009	A009/NM14/YG/01/H CEFTRIAXON	M.I.BIOPHARM India		105.85	107.98	105.72	108.70	102.81	101.20	104.49	106.38	102.49	104.89	105.1	2.3905065	2.2755675	Pass		9.34	Pass		9.34	Pass		105.05	Pass		
A-032	A032/NM14/YG/03/G LITRIXONE	UMEDICA LABC India		108.28	111.14	105.56	108.08	108.21	109.42	105.26	104.61	105.13	103.78	106.9	2.4015438	2.2455772	Pass		11.06	Pass		11.06	Pass		106.95	Pass		
A-045	A045/NM14/YG/04/Q Ceftriaxone	Wyanmar Phari Myanmar		96.26	96.03	105.16	101.32	101.42	99.78	99.51	105.68	103.21	101.37	101.0	3.2557728	3.2243808	Pass		6.16	Pass		6.16	Pass		100.97	Pass		
A-046	A046/NM14/YG/05/Q C-Tri	Emcure PHARN India		110.51	111.25	113.27	114.43	110.83	110.24	113.82	112.08	111.77	109.20	111.7	1.6766657	1.5005156	Pass		14.23	Pass		14.23	Pass		111.74	Pass		
A-056	A056/NM14/YG/01/H BECEF	Nectar Lifesci India		108.18	112.41	108.56	110.26	109.53	110.00	111.65	110.55	110.44	111.12	110.3	1.2998492	1.178793	Pass		11.92	Pass		11.92	Pass		110.27	Pass		
A-073	B-073/NM14/YG/01/I POWERCEF	WOCKHARDT Li India		107.90	109.01	108.50	111.99	111.01	110.76	110.67	107.67	107.91	109.79	109.5	1.5341904	1.4008147	Pass		11.96	Pass		11.96	Pass		109.52	Pass		
A-081	A081/NM14/YG/02/H LYFAXONE	LYKA LABS LIMI India		106.00	102.23	104.36	109.30	106.48	110.40	108.38	105.97	104.48	105.96	106.4	2.4501827	2.3037993	Pass		10.78	Pass		10.78	Pass		106.35	Pass		
A-082	A082/NM14/YG/02/H Oframax	RANBAXY LABC India		103.21	107.15	111.10	106.50	108.35	105.71	103.68	112.17	106.11	111.17	107.5	3.1308773	2.9120295	Pass		12.41	Pass		12.41	Pass		107.52	Pass		
A-103	A103/NM14/YG/02/H BECEF	Nectar Lifesci India		108.10	105.28	110.35	104.52	110.46	105.80	106.02	106.84	106.12	107.00	107.0	2.0181697	1.8853136	Pass		10.34	Pass		10.34	Pass		107.05	Pass		
A-109	A109/NM14/YG/02/Q BECEF	Nectar Lifesci India		111.31	113.98	112.48	113.15	112.38	109.38	109.94	109.62	108.23	110.86	111.1	1.8530369	1.6674377	Pass		14.04	Pass		14.04	Pass		111.13	Pass		
A-013	A013/NM14/YG/01/H LYFAXONE	LYKA LABS LIMI India		94.63	102.90	96.61	98.98	97.82	103.60	92.65	96.80	100.11	95.75	98.0	3.4824192	3.5541425	Pass		8.85	Pass		8.85	Pass		97.98	Pass		
B-024	B-024/NM14/YG/06/(Ceftriaxone	Wyanma Phari Myanmar		102.71	98.63	104.18	103.42	102.42	103.75	105.73	102.97	102.37	112.55	103.9	3.5430774	3.4109775	Pass		10.90	Pass		10.90	Pass		103.87	Pass		
B-032	B-032/NM14/YG/01/I Oframax	RANBAXY LABA India		110.28	104.87	106.17	106.59	105.97	106.34	108.70	107.96	105.27	107.96	107.0	1.6789096	1.568919	Pass		9.53	Pass		9.53	Pass		107.01	Pass		
B-039	B-039/NM14/YG/01/I Oframax	RANBAXY LABA India		106.22	109.23	110.80	106.04	107.99	105.95	106.38	109.92	104.93	105.62	107.3	2.0330108	1.8945442	Pass		10.37	Pass		10.37	Pass		107.31	Pass		
B-055	B-055/NM14/YG/01/I BECEF	Nectar Lifesci India		101.25	101.43	100.30	100.81	105.88	99.54	99.47	102.22	102.02	106.88	102.0	2.507431	2.4587205	Pass		6.52	Pass		6.52	Pass		101.98	Pass		
B-056	B-056/NM14/YG/01/I Oframax	RANBAXY LABA India		110.41	110.13	111.47	105.49	105.83	107.83	105.51	109.49	106.90	108.44	108.1	2.18673	2.0219736	Pass		11.14	Pass		11.14	Pass		108.15	Pass		
B-057	B-057/NM14/YG/01/I ZEFONE	Cadila Health India		111.36	106.88	107.80	109.84	104.50	108.12	106.75	106.56	108.64	115.63	108.6	3.1106839	2.8605828	Pass		14.55	Pass		14.55	Pass		108.61	Pass		
B-061	B-061/NM14/YG/01/(LYFAXONE	LYKA LABS LIMI India		106.00	105.14	105.92	107.70	105.27	107.78	107.32	105.02	105.71	106.73	106.3	1.0525429	0.9905438	Pass		7.76	Pass		7.76	Pass		106.26	Pass		
B-062	B-062/NM14/YG/01/(Oframax	RANBAXY LABA India		106.32	107.39	108.88	104.83	108.49	108.77	109.36	107.41	103.07	106.87	107.1	1.9777604	1.8459934	Pass		10.25	Pass		10.25	Pass		107.14	Pass		
B-073	B-073/NM14/YG/01/I POWERCEF	WOCKHARDT Li India		101.75	100.85	100.83	100.81	99.60	98.52	96.52	101.97	97.38	99.22	99.7	1.8352227	1.839889	Pass		5.44	Pass		5.44	Pass		99.75	Pass		
B-083	B-083/NM14/YG/01/(BECEF	Nectar Lifesci India		107.99	107.29	104.44	103.85	108.00	105.91	108.69	104.77	105.71	108.60	106.5	1.8121895	1.7011966	Pass		9.35	Pass		9.35	Pass		106.52	Pass		
B-087	B-087/NM14/YG/04/I TRAXONE	Korea Pharma Korea		98.19	97.05	98.98	100.26	103.23	99.78	100.37	104.65	102.74	104.84	101.0	2.7091045	2.6820334	Pass		6.50	Pass		6.50	Pass		101.01	Pass		
B-103	B-103/NM14/YG/01/(Oframax	RANBAXY LABA India		107.53	106.38	108.51	109.16	109.26	109.78	111.26	109.71	110.73	6.75	98.9	32.412876	32.770953	Pass		77.79	Fail	Fail	77.79	Fail	Fail	98.91	Pass		Fail
B-112	B-112/NM14/YG/05/(Oframax	RANBAXY LABA India		99.98	99.91	105.18	101.63	95.14	103.85	102.05	98.52	102.12	99.73	100.8	2.8335197	2.8107222	Pass		6.80	Pass		6.80	Pass		100.81	Pass		
*B-103	B-103/NM14/YG/01/(Oframax	RANBAXY LABA India		102.7	108.6	105.1	104.4	102.5	105.8	104.2	108.7	107.0	112.1	106.1	3.0	2.8	Pass		11.8	Pass								

Annex 1.9 To observed unacceptable samples with new (considered) judge

Cefuroxime tablets Myanmar project 2014

ID	Serial No.	Sample Code	Trade name of the product	Name of Manufacturer	Manufacturing Country	% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Initial Judge	New Judge
3	A-005	A005/MM14/YG/01/HG/	SPIZEF	Orchid HEALTHCA	India	101.01	96.57	95.96	96.92	99.78	95.69	97.65	2.2	2.26	Pass	
4	A-006	A006/MM14/YG/01/HG/	Zinnat	GlaxoSmithKline	UK	77.86	86.26	87.94	87.54	91.17	91.77	87.09	5.01	5.75	Pass	
5	A-007	A007/MM14/YG/01/HG/	ZIFTUM 250	Alkem Laboratori	India	94.80	96.21	95.20	98.97	95.40	97.02	96.27	1.54	1.60	Pass	
6	A-016	A016/MM14/YG/01/HG/	ZiNNASAV-250	SAVIOUR PHARMA	India	86.13	86.73	80.62	77.52	85.79	82.70	83.25	3.66	4.39	Pass	
7	A-017	A017/MM14/YG/01/HG/	ZIFATIL-250	Galpha Laborato	India	108.91	95.81	110.33	106.09	107.70	113.48	107.05	6.06	5.66	Pass	
8	A-018	A018/MM14/YG/01/HG/	CETIL	LUPIN LTD.	India	100.74	93.64	93.71	101.42	102.10	97.87	98.25	3.82	3.89	Pass	
9	A-019	A019/MM14/YG/01/HG/	FUROCEF	RENATA LIMITED	Bangladesh	69.59	77.86	74.23	86.87	83.51	82.50	79.09	6.43	8.13	Pass	
10	A-025	A025/MM14/YG/04/C/CX	SPIZEF	Orchid HEALTHCA	India	84.11	96.75	94.19	78.87	95.81	91.57	90.22	7.18	7.96	Pass	
11	A-030	A030/MM14/YG/02/C/CX	RUFEX-250	Global Pharma H	India	80.68	87.20	71.81	60.60	86.93	77.86	77.52	10.11	13.05	Fail	Pass
12	A-036	A036/MM14/YG/01/Ocl	ZIFTUM 250	Alkem Laboratori	India	100.40	94.87	87.70	95.28	92.61	92.96	93.97	4.15	4.41	Pass	
13	A-037	A037/MM14/YG/01/Ocl/	Cefusan 250	SRS pharmaceuti	India	94.46	94.66	96.71	95.89	95.55	93.84	95.19	1.05	1.11	Pass	
14	A-048	A048/MM14/YG/06/C/CX	RUFEX-250	Global Pharma H	India	66.77	63.95	65.56	66.37	66.57	68.99	66.37	1.65	2.48	Fail	Pass
15	A-052	A052/MM14/YG/02/HG/	ZIFTUM 250	Alkem Laboratori	India	96.81	97.35	98.50	97.22	100.85	101.05	98.63	1.88	1.91	Pass	
16	A-054	A054/MM14/YG/02/C/CX	ZIFTUM 250	Alkem Laboratori	India	96.88	100.24	93.79	97.82	98.63	98.83	97.70	2.22	2.27	Pass	
17	A-057	A057/MM14/YG/01/HP/(	RUFEX-250	Global Pharma H	India	51.24	71.52	79.71	71.72	79.92	72.54	71.11	10.48	14.73	Fail	Pass
18	A-058	A058/MM14/YG/HP/CXM	Zinnat	GlaxoSmithKline	UK	94.19	91.57	91.17	88.14	96.81	93.39	92.55	2.96	3.20	Pass	
19	A-063	A063/MM14/YG/01/Ocl/	ZIFTUM 250	ALKEM LABORATO	India	101.01	93.84	91.59	92.00	94.39	95.89	94.79	3.43	3.62	Pass	
20	A-068	A068/MM14/YG/02/C/CX	RUFEX-250	Global Pharma H	India	78.46	80.68	70.40	63.34	69.59	71.61	72.35	6.32	8.74	Fail	Pass
21	A-071	A071/MM14/YG/01/HG/	ZIFTUM 250	ALKEM LABORATO	India	96.61	96.68	104.14	97.82	92.78	94.40	97.07	3.91	4.03	Pass	
22	A-074	A074/MM14/YG/01/C/CX	ZIFTUM 250	ALKEM LABORATO	India	90.77	91.98	87.74	91.17	88.88	86.73	89.54	2.08	2.32	Pass	
23	A-079	A079/MM14/YG/02/Ocl/	RUFEX-250	Global Pharma H	India	64.69	62.27	63.95	81.09	58.91	62.00	65.48	7.90	12.07	Fail	Pass
24	A-085	A085/MM14/YG/02/HP/(	RUFEX-250	Global Pharma H	India	64.35	59.23	66.88	59.03	63.94	70.22	63.94	4.35	6.80	Fail	Pass
25	A-086	A086/MM14/YG/02/HP/(	Zinnat	GlaxoSmithKline	UK	82.97	81.89	85.32	89.62	85.12	87.94	85.48	2.92	3.41	Pass	
26	A-089	A089/MM14/YG/01/W/C	Cefotil	SQUARE PHARMA(	Bangladesh	BP	–	–	–	–	–	–	–	–	–	
27	A-095	A095/MM14/YG/03/W/C	KEFROX	CCL Pharmaceutic	Pakistan	BP	–	–	–	–	–	–	–	–	–	
28	A-099	A099/MM14/YG/01/HG/	RUFEX-500	Global Pharma H	India	65.56	57.43	52.65	66.16	62.13	64.55	61.41	5.34	8.70	Fail	Pass
29	A-102	A102/MM14/YG/01/Ocl/	CETIL	LUPIN LTD.	India	73.42	72.28	70.60	76.05	70.80	69.66	72.14	2.33	3.24	Pass	
30	A-104	A104/MM14/YG/02/HP/(	ZIFTUM 250	ALKEM LABORATO	India	106.90	103.07	100.65	105.99	99.03	106.29	103.65	3.28	3.16	Pass	
32	B-002	B-002/MM14/YG/01/HP/	ZIFTUM 250	Alkem Laboratori	India	126.66	131.50	131.09	122.42	131.30	136.54	129.92	4.83	3.71	Pass	
33	B-003	B-003/MM14/YG/01/HP/	SPIZEF	Orchid HEALTHCA	India	98.43	96.21	94.60	92.78	96.41	94.19	95.44	1.99	2.08	Pass	
34	B-004	B-004/MM14/YG/01/HP/	CETIL	LUPIN LTD.	India	73.42	74.84	73.89	75.31	80.48	74.23	75.36	2.60	3.44	Pass	
35	B-023	B-023/MM14/YG/07/C/C	RUFEX	Global Pharma H	India	62.33	64.15	62.13	65.36	65.09	63.34	63.73	1.37	2.14	Fail	Pass
36	B-027	B-027/MM14/YG/01/C/C	Zinnat	GlaxoSmithKline	UK	91.77	93.19	89.96	87.74	94.19	93.59	91.74	2.48	2.70	Pass	
37	B-029	B-029/MM14/YG/02/C/C	ZIFTUM 250	Alkem Laboratori	India	80.88	82.50	81.15	89.62	85.12	87.94	84.54	3.65	4.32	Pass	
38	B-030	B-030/MM14/YG/08/C/C	Zinnat	GlaxoSmithKline	UK	89.54	79.58	89.54	84.29	86.06	82.99	85.33	3.89	4.56	Pass	
39	B-031	B-031/MM14/YG/08/C/C	ZIFTUM 250	Alkem Laboratori	India	98.83	97.02	97.42	97.22	101.25	96.41	98.02	1.77	1.81	Pass	
40	B-034	B-034/MM14/YG/01/HP/	ZIFTUM 250	Alkem Laboratori	India	95.14	97.46	98.14	92.41	96.51	96.92	96.10	2.07	2.15	Pass	
41	B-038	B-038/MM14/YG/01/HP/	ZIFTUM 250	Alkem Laboratori	India	127.26	122.02	127.47	124.04	122.09	123.84	124.45	2.41	1.94	Pass	
42	B-042	B-042/MM14/YG/01/HG	ZIFATIL	Galpha Laborato	India	88.93	88.31	84.83	87.43	90.36	90.77	88.44	2.16	2.45	Pass	
43	B-044	B-044/MM14/YG/01/HG	Zinmax	DOMESCO MEDICA	VietNam	90.77	91.17	92.38	88.55	89.15	89.56	90.26	1.43	1.58	Pass	
44	B-047	B-047/MM14/YG/01/C/C	RUFEX	Global Pharma H	India	60.52	59.51	59.71	62.94	60.52	60.32	60.59	1.23	2.03	Fail	Pass
45	B-052	B-052/MM14/YG/01/HP/	CETIL	LUPIN LTD.	India	109.12	107.50	103.74	100.18	112.14	105.89	106.43	4.19	3.93	Pass	
46	B-053	B-053/MM14/YG/01/HP/	Zinnat	GlaxoSmithKline	UK	88.75	94.19	86.13	79.67	74.43	88.35	85.25	7.08	8.31	Pass	
47	B-063	B-063/MM14/YG/01/O(c	ZIFTUM 250	Alkem Laboratori	India	93.43	88.93	105.52	98.14	93.23	103.13	97.06	6.38	6.57	Pass	
48	B-066	B-066/MM14/YG/01/C/C	ZIFTUM 250	Alkem Laboratori	India	91.59	87.90	96.92	95.69	94.25	100.60	94.49	4.39	4.65	Pass	
49	B-067	B-067/MM14/YG/01/C/C	RUFEX-250	Global Pharma H	India	84.92	72.82	78.46	81.96	77.66	79.67	79.25	4.10	5.18	Pass	
50	B-076	B-076/MM14/YG/01/HG	ZIFTUM 250	Alkem Laboratori	India	99.23	92.98	93.99	95.60	94.19	96.21	95.37	2.22	2.33	Pass	
51	B-079	B-079/MM14/YG/01/O(c	ZIFTUM 250	Alkem Laboratori	India	93.39	93.99	90.36	91.57	92.98	95.47	92.96	1.80	1.94	Pass	
52	B-080	B-080/MM14/YG/01/O(c	Zinnat	GlaxoSmithKline	UK	91.37	89.76	83.10	91.77	86.33	90.97	88.88	3.45	3.88	Pass	
53	B-086	B-086/MM14/YG/03/C/C	Zinnat	GlaxoSmithKline	UK	77.26	88.61	85.19	80.88	82.50	81.15	82.60	3.91	4.73	Pass	
54	B-089	B-089/MM14/YG/04/W/	Zinnat	GlaxoSmithKline	UK	77.66	89.89	75.64	81.69	73.02	78.67	79.43	5.89	7.42	Pass	
55	B-093	B-093/MM14/YG/01/C/C	RUFEX	Global Pharma H	India	65.56	64.75	87.54	85.12	81.49	89.76	79.04	11.10	14.04	Fail	Pass
56	B-100	B-100/MM14/YG/04/C/C	ZIFTUM 250	Alkem Laboratori	India	100.04	98.43	100.04	98.83	96.41	102.06	99.30	1.90	1.91	Pass	
57	B-101	B-101/MM14/YG/05/C/C	Zinnat	GlaxoSmithKline	UK	89.15	85.52	92.51	88.35	89.15	91.17	89.31	2.41	2.70	Pass	
58	B-102	B-102/MM14/YG/02/C/C	Zinnat	GlaxoSmithKline	UK	83.91	89.62	87.81	88.28	95.60	91.37	89.43	3.91	4.37	Pass	
59	B-104	B104/MM14/YG/01/HG/	ZIFTUM 250	Alkem Laboratori	India	94.80	98.23	90.36	93.99	96.01	92.18	94.26	2.78	2.95	Pass	
60	B-111	B111/MM14/YG/02/C/CX	RUFEX-250	Global Pharma H	India	76.91	67.63	74.18	89.13	89.13	85.99	80.50	8.92	11.08	Pass	
1	PA-001	PA001/MM14/YG/01/C/C	ZIFTUM 250	Alkem Laboratori	India	158.05	134.52	153.14	152.94	136.54	146.22	146.90	9.60	6.53	Pass	
2	PA-002	PA002/MM14/YG/01/C/C	SPIZEF	Orchid HEALTHCA	India	73.83	98.97	100.24	97.22	85.79	83.04	89.85	10.63	11.83	Pass	
31	PB-001	PB-001/MM14/YG/01/O(	ZINNASAV-250	SAVIOUR PHARMA	India	75.96	82.78	83.19	85.86	82.58	81.35	81.95	3.29	4.02	Pass	

% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge at 45分	New Judge at 45分	Initial Final Judge	New Final Judge
97.95	96.71	96.10	96.71	99.30	95.48	97.04	1.38	1.42	Pass		Pass	
94.60	103.07	95.00	96.41	100.44	100.65	98.36	3.49	3.55	Pass		Pass	
99.23	107.50	106.29	107.91	104.68	105.28	105.15	3.15	3.00	Pass		Pass	
94.40	95.20	88.14	85.52	95.20	87.14	90.93	4.47	4.92	Pass		Pass	
116.37	109.32	111.27	108.17	112.27	115.97	112.23	3.38	3.01	Pass		Pass	
108.38	100.40	100.19	104.49	101.83	102.04	102.89	3.10	3.01	Pass		Pass	
80.88	86.53	87.54	100.51	100.85	92.58	91.48	8.04	8.78	Pass		Pass	
97.55	100.85	92.98	81.29	97.82	96.01	94.42	6.92	7.33	Pass		Pass	
91.57	91.57	76.25	93.05	90.97	93.79	89.53	6.59	7.36	Pass		Fail	Pass
106.13	101.56	94.05	102.24	103.26	101.22	101.41	4.02	3.96	Pass		Pass	
96.92	100.26	97.94	98.76	104.70	97.80	99.40	2.83	2.85	Pass		Pass	
85.93	87.54	85.72	85.93	88.14	88.82	87.01	1.33	1.53	Pass		Fail	Pass
102.86	101.65	107.77	101.92	107.17	103.13	104.09	2.69	2.58	Pass		Pass	
105.28	106.90	101.86	105.69	103.67	104.48	104.65	1.75	1.67	Pass		Pass	
79.03	83.19	81.56	85.65	90.91	84.01	84.06	4.04	4.81	Fail	Pass	Fail	Pass
101.25	101.65	98.43	98.02	102.06	100.04	100.24	1.71	1.70	Pass		Pass	
109.41	100.33	99.17	97.53	106.13	102.24	102.47	4.51	4.40	Pass		Pass	
86.06	85.93	75.44	89.35	91.57	91.37	86.62	6.01	6.93	Fail	Pass	Fail	Pass
102.86	101.86	92.51	103.67	97.82	102.86	100.27	4.33	4.32	Pass		Pass	
99.84	100.04	90.77	95.81	96.21	93.79	96.08	3.56	3.71	Pass		Pass	
77.05	83.44	73.29	86.73	69.79	75.64	77.66	6.34	8.17	Fail	Pass	Fail	Pass
86.47	78.89	91.18	79.23	84.22	90.57	85.09	5.34	6.27	Fail	Pass	Fail	Pass
96.21	96.81	99.84	99.71	98.02	96.28	97.81	1.65	1.69	Pass		Pass	
90.56	93.19	91.57	94.80	96.41	95.81	93.72	2.35	2.51	Pass		Pass	
97.29	98.36	100.04	100.31	91.17	93.39	96.76	3.71	3.84	Pass		Pass	
84.72	83.91	84.51	86.93	82.09	86.26	84.74	1.72	2.04	Pass		Fail	Pass
99.44	93.39	98.23	99.44	94.80	96.41	96.95	2.51	2.59	Pass		Pass	
107.70	105.82	106.70	118.19	102.66	110.80	108.64	5.37	4.94	Pass		Pass	
117.58	121.01	117.18	119.40	115.16	118.93	118.21	2.03	1.71	Pass		Pass	
101.45	97.02	95.20	99.84	97.62	100.24	98.56	2.34	2.37	Pass		Pass	
98.56	93.79	87.94	95.00	99.44	97.02	95.29	4.18	4.38	Pass		Pass	
82.90	84.31	81.49	81.29	84.31	89.56	83.98	3.03	3.61	Pass		Fail	Pass
100.24	104.95	98.83	97.96	100.65	100.44	100.51	2.41	2.40	Pass		Pass	
104.88	97.82	104.28	103.87	104.88	102.33	103.01	2.71	2.63	Pass		Pass	
97.32	96.92	97.73	96.10	95.48	95.28	96.47	1.01	1.04	Pass		Pass	
104.48	125.11	103.47	107.91	125.45	103.67	111.68	10.66	9.54	Pass		Pass	
100.40	105.31	105.31	99.10	98.28	101.01	101.57	3.05	3.01	Pass		Pass	
119.20	123.03	124.24	116.58	119.00	112.54	119.10	4.27	3.59	Pass		Pass	
92.00	97.53	92.41	93.16	92.82	99.37	94.55	3.10	3.28	Pass		Pass	
102.06	105.08	99.84	101.52	100.78	100.38	101.61	1.88	1.85	Pass		Pass	
83.04	80.48	85.93	83.71	81.02	81.89	82.68	2.00	2.41	Pass		Fail	Pass
108.31	105.89	102.06	107.30	106.16	100.85	105.09	2.97	2.83	Pass		Pass	
102.66	106.09	95.00	95.00	91.44	96.21	97.73	5.50	5.62	Pass		Pass	
101.83	95.28	112.89	103.06	116.58	110.57	106.70	7.98	7.48	Pass		Pass	
96.30	96.44	107.22	103.06	105.52	108.73	102.88	5.38	5.23	Pass		Pass	
97.15	90.77	94.60	96.01	93.99	96.81	94.89	2.37	2.49	Pass		Pass	
108.51	103.67	105.69	108.11	83.10	104.81	102.32	9.60	9.38	Pass		Pass	
105.89	102.66	100.04	101.25	102.86	104.68	102.90	2.15	2.09	Pass		Pass	
101.18	98.23	95.00	108.17	96.41	100.65	99.94	4.68	4.69	Pass		Pass	
90.97	98.02	99.37	94.40	88.75	97.29	94.80	4.22	4.45	Pass		Pass	
93.79	101.25	97.89	100.04	94.40	97.62	97.50	2.97	3.05	Pass		Pass	
71.47	72.62	94.73	91.50	87.34	91.57	84.87	10.22	12.04	Fail	Pass	Fail	Pass
104.28	100.04	103.13	103.27	103.67	108.11	103.75	2.59	2.50	Pass		Pass	
102.53	97.82	97.82	99.30	82.50	100.11	96.68	7.16	7.41	Pass		Pass	
97.02	102.60	99.44	99.03	85.12	98.02	96.87	6.06	6.25	Pass		Pass	
103.81	108.71	101.45	102.26	107.30	97.62	103.53	4.05	3.91	Pass		Pass	
90.84	86.06	85.86	90.16	91.80	91.39	89.35	2.68	3.00	Pass		Pass	
125.25	126.12	123.63	124.24	117.18	120.61	122.84	3.35	2.73	Pass		Pass	
79.81	100.23	100.71	99.97	87.07	85.32	92.19	9.21	10.00	Fail	Pass	Fail	Pass
79.44	91.18	90.57	89.95	86.47	90.02	87.94	4.48	5.09	Fail	Pass	Fail	Pass

% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	% of Quantity Tablet 7	% of Quantity Tablet 8	% of Quantity Tablet 9	% of Quantity Tablet 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge	New Judge AV=18
104.92	104.54	100.00	102.70	95.88	99.40	94.86	105.87	101.22	96.94	100.6	3.9	3.9	9.372893126	Pass	
104.21	103.39	98.63	97.51	93.65	103.10	106.08	98.50	95.83	102.27	100.3	4.1	4.0	9.731768808	Pass	
102.27	103.86	100.48	102.58	98.18	97.12	100.36	100.98	97.48	92.73	99.6	3.3	3.3	7.89	Pass	
92.41	93.57	91.85	95.51	95.75	90.01	89.77	84.34	88.41	101.55	92.3	4.7	5.1	17.48	Fail	Pass
84.42	99.25	100.84	85.26	90.85	90.97	97.08	91.92	93.14	92.91	92.7	5.4	5.8	18.72	Fail	Fail
85.61	97.53	104.85	104.61	90.77	107.86	98.31	94.87	97.54	98.02	98.0	6.7	6.8	16.58	Fail	Pass
99.58	97.87	93.20	95.87	93.71	103.43	100.62	95.39	98.09	95.14	97.3	3.2	3.3	9.00	Pass	
94.08	101.01	89.89	94.86	93.99	95.64	99.03	101.53	94.92	92.86	95.8	3.7	3.8	11.55	Pass	
92.98	91.66	89.14	90.87	92.74	88.74	88.45	86.30	82.74	82.84	88.6	3.7	4.2	18.76	Fail	Fail
104.08	102.32	92.47	95.41	111.73	93.88	93.39	101.14	92.26	94.69	98.1	6.4	6.6	15.45	Fail	Pass
91.27	93.27	96.13	88.28	98.09	91.63	91.59	94.10	87.74	79.11	91.1	5.3	5.8	20.06	Fail	Fail
95.65	100.96	82.79	86.92	84.50	92.64	87.53	87.83	84.09	83.79	88.7	5.9	6.7	24.08	Fail	Fail
92.28	99.85	94.71	96.54	95.82	98.57	99.74	103.67	107.73	105.66	99.5	5.0	5.0	11.90	Pass	
101.48	100.22	91.88	103.28	95.38	105.52	97.11	98.08	92.65	95.07	98.1	4.5	4.6	11.28	Pass	
87.87	87.87	87.65	82.96	87.90	82.50	85.36	79.08	77.86	80.46	84.0	3.9	4.7	23.95	Fail	Fail
95.38	104.18	100.01	98.10	103.39	99.45	93.58	100.25	90.67	91.76	97.7	4.7	4.8	12.04	Pass	
99.58	95.59	96.90	102.68	100.60	103.08	94.12	99.93	98.40	95.48	98.6	3.1	3.1	7.38	Pass	
85.13	80.97	74.62	–	–	–	–	–	–	–	80.2	–	–	–	–	
107.29	97.04	100.25	99.21	101.42	104.80	95.76	99.53	94.60	89.71	99.0	5.1	5.1	12.13	Pass	
105.17	99.99	101.85	103.65	98.37	100.92	98.68	93.11	93.86	98.67	99.4	3.8	3.9	9.21	Pass	
86.23	86.08	82.00	86.17	84.76	88.14	83.31	89.02	81.19	82.07	84.9	2.7	3.2	20.05	Fail	Fail
98.68	88.40	99.10	101.87	98.65	93.01	98.22	95.66	96.45	97.29	96.7	3.7	3.9	10.77	Pass	
94.85	92.47	90.91	95.96	99.71	94.09	96.69	97.74	93.76	94.46	95.1	2.6	2.7	9.60	Pass	
97.95	97.60	93.43	92.10	101.08	87.19	96.73	96.72	93.55	94.45	95.1	3.8	4.0	12.63	Pass	
89.41	99.51	95.97	94.42	103.65	96.10	90.11	97.75	94.44	90.99	95.2	4.4	4.6	13.88	Pass	
79.62	80.37	82.34	80.60	76.43	78.62	81.50	79.29	78.70	75.53	79.3	2.1	2.7	24.28	Fail	Fail
98.44	99.04	95.46	93.58	98.00	95.74	100.25	97.12	98.56	87.30	96.3	3.7	3.9	11.12	Pass	
103.02	98.07	99.18	103.84	101.83	103.11	94.54	97.96	102.81	97.01	100.1	3.2	3.2	7.67	Pass	
96.55	104.47	106.58	100.60	100.41	102.25	90.34	103.61	96.69	99.31	100.1	4.7	4.7	11.27	Pass	
94.9	96.3	96.4	94.2	99.8	100.9	95.0	95.7	91.2	103.1	96.7	3.5	3.6	10.22	Pass	
98.99	100.25	99.81	95.66	94.94	97.36	89.83	90.59	94.11	93.58	95.5	3.6	3.8	11.71	Pass	
86.47	88.94	86.99	95.59	93.94	92.55	73.24	90.08	89.30	82.01	87.9	6.5	7.4	26.13	Fail	Fail
96.26	93.06	95.03	91.98	95.18	90.38	93.66	86.06	98.76	92.34	93.3	3.5	3.7	13.57	Pass	
98.08	99.17	97.64	88.44	89.52	93.13	83.94	84.61	78.65	95.15	90.8	6.9	7.6	24.34	Fail	Fail
97.84	98.27	109.33	101.97	98.36	104.72	97.52	111.74	108.12	93.15	102.1	6.1	6.0	15.27	Pass	
96.67	101.02	94.08	96.38	93.86	95.06	93.75	96.25	96.24	97.52	96.1	2.2	2.3	7.63	Pass	
101.07	100.73	104.94	106.81	101.49	97.11	102.96	106.33	102.82	102.79	102.7	2.9	2.8	8.11	Pass	
105.30	92.74	104.55	105.08	97.92	98.05	98.24	100.54	98.83	98.10	99.9	4.0	4.0	9.59	Pass	
83.66	84.52	86.32	91.22	84.44	85.86	91.58	84.65	93.10	80.82	86.6	4.0	4.6	21.48	Fail	Fail
102.47	102.35	102.44	104.48	103.97	103.72	102.78	98.97	97.20	96.30	101.5	2.9	2.9	6.98	Pass	
71.12	69.88	88.62	76.65	74.10	77.86	88.15	85.61	73.36	74.00	77.9	7.0	9.0	37.37	Fail	Fail
91.71	97.36	88.44	93.86	88.52	96.88	92.86	90.31	92.94	92.51	92.5	3.0	3.3	13.24	Pass	
104.46	85.18	85.58	83.73	90.96	104.88	89.09	90.42	102.98	103.08	94.0	8.8	9.3	25.50	Fail	Fail
98.72	91.94	97.51	92.91	97.18	91.92	109.19	92.38	98.29	102.77	97.3	5.5	5.7	14.50	Pass	
97.47	99.41	97.77	99.32	92.59	92.40	94.94	95.56	96.13	101.41	96.7	2.9	3.0	8.88	Pass	
97.63	100.15	107.00	101.46	107.64	106.13	101.37	101.88	100.85	101.86	102.6	3.2	3.2	8.89	Pass	
97.22	96.14	92.13	89.04	90.90	91.00	95.82	93.73	84.56	92.74	92.3	3.8	4.1	15.21	Pass	
101.08	94.44	98.21	99.11	103.97	102.67	97.27	97.77	97.49	97.75	99.0	2.8	2.9	6.80	Pass	
97.64	99.42	97.71	100.36	97.58	96.02	98.42	96.52	96.50	96.74	97.7	1.4	1.4	4.12	Pass	
92.29	98.58	98.56	91.81	102.01	90.37	90.05	93.33	92.23	94.00	94.3	4.0	4.3	13.81	Pass	
109.93	105.57	104.26	115.00	103.68	107.96	107.55	110.73	101.57	102.22	106.8	4.2	4.0	15.48	Pass	
88.76	91.12	80.84	80.41	75.56	87.75	83.93	82.01	89.50	86.58	84.6	4.9	5.8	25.68	Fail	Fail
93.01	94.13	107.34	91.54	94.24	102.22	93.05	92.89	89.85	90.01	94.8	5.6	5.9	17.08	Fail	Pass
101.68	103.63	103.61	99.44	102.50	115.40	101.56	97.35	95.65	98.59	101.9	5.4	5.3	13.47	Pass	
94.09	96.03	98.31	97.15	93.26	92.67	95.69	99.97	95.30	96.11	95.9	2.2	2.3	8.01	Pass	
99.74	105.46	105.23	100.22	101.84	95.14	97.11	101.63	90.14	102.08	99.9	4.7	4.7	11.22	Pass	
77.76	80.96	83.08	77.55	76.53	76.92	78.97	79.20	74.70	77.48	78.3	2.4	3.0	25.88	Fail	Fail
93.01	94.13	101.56	91.54	94.24	102.22	93.05	92.89	89.85	90.01	94.3	4.3	4.6	14.57	Pass	
103.65	100.90	102.00	99.25	97.83	96.97	102.27	102.52	93.13	99.91	99.8	3.2	3.2	7.64	Pass	
88.20	90.25	93.58	92.14	90.62	79.25	94.40	95.94	85.54	88.40	89.83	4.87	5.42	20.36	Fail	Fail

% of Quantity Tablet 1	% of Quantity Tablet 2	% of Quantity Tablet 3	% of Quantity Tablet 4	% of Quantity Tablet 5	% of Quantity Tablet 6	% of Quantity Tablet 7	% of Quantity Tablet 8	% of Quantity Tablet 9	% of Quantity Tablet 10	% of Quantity Tablet 11	% of Quantity Tablet 12	% of Quantity Tablet 13	% of Quantity Tablet 14	% of Quantity Tablet 15	% of Quantity Tablet 16	% of Quantity Tablet 17	% of Quantity Tablet 18	% of Quantity Tablet 19	% of Quantity Tablet 20	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge for Content Uniformity	New Judge for Content Uniform
																								Pass	
																								Pass	
																								Pass	
																								Pass	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Fail
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Pass	
																								Pass	
																								Pass	
92.27	92.42	92.10	92.27	92.68	91.66	88.43	90.69	83.91	80.84	91.06	90.78	85.74	85.97	87.09	82.13	85.49	81.53	83.53	89.05	88.51	3.94	4.46	17.88	Fail	Pass
																								Pass	
103.74	97.31	100.95	96.99	97.34	94.32	93.53	99.38	94.32	100.71	97.08	90.13	99.63	93.98	97.15	83.28	93.22	92.56	90.18	97.62	94.15	5.19	5.51	14.72	Pass	
106.26	97.80	101.48	92.52	100.54	104.06	101.64	85.36	104.57	99.83	88.92	94.43	94.28	95.97	91.60	94.93	95.01	93.71	104.98	91.35	94.22	6.92	7.34	18.11	Fail	Fail
																								Pass	
																								Pass	
80.29	84.28	77.86	84.57	81.54	82.89	80.56	76.34	77.11	77.13	83.49	83.87	86.29	80.73	85.28	83.90	86.82	83.35	82.47	86.22	82.88	3.48	4.20	22.58	Fail	Fail
																								Pass	
																								Pass	
																								Fail	
																								Pass	
																								Pass	
93.91	93.25	92.28	91.09	92.01	88.91	88.93	87.13	85.26	84.35	80.02	81.23	81.78	80.43	80.19	85.20	83.08	81.62	79.76	82.18	85.72	4.24	4.95	21.27	Fail	Fail
																								Pass	
																								Pass	
																								Pass	
																								Pass	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Fail
																								Pass	
																								Pass	
																								Pass	
																								Pass	
																								Pass	
																								Fail	Fail
																								Pass	
104.55	104.39	102.58	105.96	95.19	105.45	101.98	103.07	103.88	95.14	107.70	105.54	100.46	96.45	103.95	104.83	102.13	102.19	99.40	103.23	98.84	6.98	7.06	13.96	Pass	
																								Pass	
																								Pass	
																								Pass	
																								Pass	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Fail
																								Pass	
																								Fail	Fail
																								Pass	
106.32	96.25	95.82	97.59	99.85	102.09	97.49	91.39	98.72	96.62	92.69	93.54	91.32	91.09	96.74	99.63	93.44	97.31	92.81	97.83	95.20	6.01	6.31	15.32	Pass	
																								Pass	
																								Pass	
																								Pass	
																								Pass	
																								Pass	
																								Pass	
																								Pass	
92.16	91.21	87.91	88.03	88.11	86.34	86.50	83.10	88.83	91.62	84.15	84.91	76.84	79.15	85.28	78.81	85.54	81.09	78.94	82.78	85.26	4.52	5.31	22.29	Fail	Fail
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Fail	Pass
																								Pass	
																								Pass	
																								Pass	
93.21	89.27	87.18	90.76	86.50	86.94	88.76	92.50	88.72	82.25	85.54	83.32	82.14	75.51	85.60	78.09	77.83	79.58	81.52	83.49	82.84	5.17	6.25	26.01	Fail	Fail
																								Pass	
																								Pass	
85.84	88.33	107.07	89.15	94.20	89.80	87.21	89.31	87.72	84.92	90.39	84.84	89.89	95.62	94.75	99.33	94.43	79.50	89.28	96.57	90.56	5.58	6.16	19.11	Fail	Fail

Kanazawa Univ. Quantity test	Judge	New Judge	Kanazawa Univ. Quantity test 2nd	FinalJudge	w FinalJud	A I I	New A I I
100.63	Pass		-	Pass		Pass	
100.32	Pass		-	Pass		Pass	
99.60	Pass		-	Pass		Pass	
92.32	Pass		88.96	Fail	Pass	Fail	Pass
92.66	Pass		-	Pass		Fail	Fail
98.00	Pass		-	Pass		Fail	Pass
97.29	Pass		-	Pass		Pass	
95.78	Pass		-	Pass		Pass	
88.65	Fail	Pass	88.51	Fail	Pass	Fail	Pass
98.14	Pass		101.90	Pass		Pass	
91.12	Pass		94.15	Pass		Pass	
88.67	Fail	Pass	94.22	Pass		Fail	Fail
99.46	Pass		-	Pass		Pass	
98.07	Pass		-	Pass		Pass	
83.95	Fail	Pass	82.88	Fail	Pass	Fail	Fail
97.68	Pass		-	Pass		Pass	
98.64	Pass		-	Pass		Pass	
80.24	Fail	Pass	-	Fail	Pass	Fail	Pass
98.96	Pass		-	Pass		Pass	
99.43	Pass		-	Pass		Pass	
84.90	Fail	Pass	85.72	Fail	Pass	Fail	Fail
96.73	Pass		-	Pass		Pass	
95.06	Pass		-	Pass		Pass	
95.08	Pass		-	Pass		Pass	
95.24	Pass		-	Pass		Pass	
79.30	Fail	Pass	79.30	Fail	Pass	Fail	Fail
96.35	Pass		-	Pass		Pass	
100.14	Pass		-	Pass		Pass	
100.08	Pass		-	Pass		Pass	
96.72	Pass		-	Pass		Pass	
95.51	Pass		-	Pass		Pass	
87.91	Fail	Pass	87.91	Fail	Pass	Fail	Fail
93.27	Pass		-	Pass		Pass	
90.84	Pass		98.84	Pass		Pass	
102.10	Pass		-	Pass		Pass	
96.08	Pass		-	Pass		Pass	
102.71	Pass		-	Pass		Pass	
99.93	Pass		-	Pass		Pass	
86.61	Fail	Pass	86.61	Fail	Pass	Fail	Fail
101.47	Pass		-	Pass		Pass	
77.93	Fail	Pass	77.93	Fail	Pass	Fail	Fail
92.54	Pass		-	Pass		Pass	
94.04	Pass		95.20	Pass		Pass	
97.28	Pass		-	Pass		Pass	
96.70	Pass		-	Pass		Pass	
102.60	Pass		-	Pass		Pass	
92.33	Pass		-	Pass		Pass	
98.98	Pass		-	Pass		Pass	
97.69	Pass		-	Pass		Pass	
94.32	Pass		-	Pass		Pass	
106.85	Pass		-	Pass		Pass	
84.65	Fail	Pass	85.26	Fail	Pass	Fail	Fail
94.83	Pass		-	Pass		Fail	Pass
101.94	Pass		-	Pass		Pass	
95.14	Pass		-	Pass		Pass	
99.86	Pass		-	Pass		Pass	
78.32	Fail	Pass	82.84	Fail	Pass	Fail	Fail
94.25	Pass		-	Pass		Pass	
99.84	Pass		-	Pass		Pass	
89.83	Pass		90.56	Pass		Fail	Fail

Omeprazole BP

Serial No .	Sample Code	Trade name of the	Name of Manufacturer	Manufactu	% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	New Judge 10% *1.2= 12% dissolved
A-096	A096/MM14/YG/	Omep-20	ARISTOPHARMA LTD.	Banglade	22.3	10.4	8.9	11.6	9.6	10.2	12.2	5.0	41.4	Fail	Fail
B-065	B-065/MM14/YG,	Omep	ARISTOPHARMA LTD.	Banglade	11.1	11.3	10.9	11.0	11.2	10.9	11.1	0.2	1.7	Fail	Pass
A-076	A076/MM14/YG/	ASMOZOL-20	ASMOH LABORATORIES LTD.	India	1.4	1.4	1.4	1.4	1.4	1.4	1.4	0.0	0.0	Pass	
B-092	B-092/MM14/YG,	OMEPREN	BLUE CROSS LABORATORIES LTD.	India	2.5	2.4	1.8	1.1	1.2	1.2	1.7	0.6	36.5	Pass	
B-098	B-098/MM14/YG,	OMEPREN	BLUE CROSS LABORATORIES LTD.	India	2.4	2.3	2.5	2.4	2.2	2.4	2.3	0.1	4.6	Pass	
B-005	B-005/MM14/YG,	OCID	Cadila Health Limited	India	6.0	3.6	3.6	3.9	5.8	4.1	4.5	1.1	24.6	Pass	
B-011	B-011/MM14/YG,	OCID	Cadila Health Limited	India	5.3	4.0	7.2	4.4	7.2	5.4	5.6	1.4	24.2	Pass	
B-070	B-070/MM14/YG,	OCID	Cadila Health Limited	India	3.7	3.9	3.8	2.5	3.1	2.5	3.3	0.6	19.7	Pass	
B-090	B-090/MM14/YG,	OCID	Cadila Health Limited	India	2.2	1.9	1.9	2.0	2.0	2.0	2.0	0.1	6.4	Pass	
PA-006	PA006/MM14/YG	OCID	Cadila Healthcare Limited	India	5.4	4.0	7.2	4.4	7.2	5.5	5.6	1.4	24.2	Pass	
A-002	A002/MM14/YG/	OCID	Cadila Healthcare Limited	India	3.0	2.7	2.6	2.6	2.5	4.0	2.9	0.6	19.1	Pass	
A-026	A026/MM14/YG/	OCID	Cadila Healthcare Limited	India	9.6	3.6	3.6	3.9	5.8	4.1	5.1	2.3	46.0	Pass	
A-042	A042/MM14/YG/	OCID	Cadila Healthcare Limited	India	5.6	5.0	3.6	3.8	5.0	5.4	4.7	0.8	17.2	Pass	
A-060	A060/MM14/YG/	OCID	Cadila Healthcare Limited	India	2.4	2.5	4.4	2.9	2.9	2.6	2.9	0.7	24.9	Pass	
A-084	A084/MM14/YG/	OCID	Cadila Healthcare Limited	India	9.9	9.5	7.3	9.6	9.7	10.0	9.3	1.0	10.8	Pass	
A-034	A034/MM14/YG/	LOMAC-20	Cipla Ltd.	India	26.9	27.7	27.7	27.3	28.1	23.5	26.9	1.7	6.3	Fail	Fail
A-038	A038/MM14/YG/	LOMAC-20	Cipla Ltd.	India	12.5	11.6	12.6	13.0	14.1	15.1	13.1	1.2	9.5	Fail	Fail
B-007	B-007/MM14/YG,	LOMAC	Cipla Ltd.	India	39.9	38.1	42.5	40.3	39.5	42.3	40.4	1.7	4.2	Fail	Fail
B-110	B110/MM14/YG/	LOMAC	Cipla Ltd.	India	24.4	25.4	25.1	24.7	25.4	21.1	24.4	1.7	6.8	Fail	Fail
PB-003	PB-003/MM14/YC	OMEZ	Dr. REDDY'S LABORATORIES	India	9.0	8.9	8.9	5.7	3.4	5.1	6.8	2.4	35.4	Pass	
B-006	B-006/MM14/YG,	OMEZ	Dr. REDDY'S LABORATORIES	India	5.8	2.9	5.3	9.1	8.8	8.7	6.8	2.5	37.1	Pass	
B-008	B-008/MM14/YG,	OMEZ	Dr. REDDY'S LABORATORIES	India	14.4	13.3	14.5	14.4	8.4	11.0	12.7	2.5	19.6	Fail	Fail
B-013	B-013/MM14/YG,	OMEZ	Dr. REDDY'S LABORATORIES	India	16.5	15.9	8.5	15.0	10.6	15.9	13.7	3.4	24.4	Fail	Fail
B-036	B-036/MM14/YG,	OMEZ	Dr. REDDY'S LABORATORIES	India	8.8	7.6	1.0	1.2	0.9	8.0	4.6	3.9	85.4	Pass	
B-054	B-054/MM14/YG,	OMEZ	Dr. REDDY'S LABORATORIES	India	22.8	26.4	28.2	24.0	25.3	27.4	25.7	2.1	8.0	Fail	Fail
B-106	B106/MM14/YG/	OMEZ	Dr. REDDY'S LABORATORIES	India	12.4	7.6	14.8	20.7	19.3	20.7	15.9	5.3	33.1	Fail	Fail
PA-005	PA005/MM14/YG	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	26.9	9.3	15.9	26.6	9.3	15.7	17.3	7.9	45.6	Fail	Fail
A-001	A001/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.8	5.9	7.5	9.3	6.9	7.4	7.8	1.5	19.1	Pass	
A-015	A015/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	14.3	9.3	16.8	15.2	15.9	9.7	13.5	3.2	23.9	Fail	Fail
A-039	A039/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.5	8.5	14.7	14.6	13.1	14.5	12.5	2.8	22.1	Fail	Fail
A-050	A050/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	10.5	9.2	20.2	17.3	17.9	24.3	16.6	5.8	34.9	Fail	Fail
A-061	A061/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.9	9.5	9.5	9.1	9.9	9.9	9.6	0.3	3.5	Pass	
A-065	A065/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	9.2	9.2	9.1	9.8	7.0	7.4	8.6	1.1	13.3	Pass	
A-101	A101/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	8.9	12.5	9.4	14.3	11.1	14.1	11.7	2.3	19.8	Fail	Pass
A-106	A106/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	1.9	1.9	1.9	1.9	1.9	1.9	1.9	0.0	0.0	Pass	
A-107	A107/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	4.8	4.7	4.6	4.5	4.6	4.4	4.6	0.1	3.3	Pass	
A-114	A114/MM14/YG/	OMEZ	Dr.REDDY'S LABORATORIES LTD.	India	1.9	1.9	1.9	1.9	1.9	1.9	1.9	0.0	0.0	Pass	
A-012	A012/MM14/YG/	Zosec	Emcure PHARMACETICALS LTD.	India	7.2	5.7	5.0	7.1	5.8	5.0	6.0	1.0	16.2	Pass	
B-017	B-017/MM14/YG,	Zosec	Emcure PHARMACEUTICAL LTD.	India	2.6	2.4	1.8	1.3	1.2	1.0	1.7	0.6	37.4	Pass	
B-037	B-037/MM14/YG,	OMFIL	Fourrts Laboratories Pvt Ltd,	India	3.5	7.1	5.1	4.2	6.8	5.0	5.3	1.4	26.7	Pass	
A-033	A033/MM14/YG/	OMFIL 20	Fourrts Laboratories Pvt.Ltd.	India	8.3	8.4	8.3	8.6	8.9	8.7	8.5	0.3	3.0	Pass	
B-045	B-045/MM14/YG,	OMPREZ	Global Pharma Healthcare Pvt, L	India	2.6	3.0	4.4	2.5	2.8	4.4	3.3	0.9	26.6	Pass	
A-041	A041/MM14/YG/	TRISEC	GREAT HIMALAYAN PTE LTD.	India	12.0	25.0	11.5	11.8	24.9	11.6	16.1	6.8	42.4	Fail	Fail
B-077	B-077/MM14/YG,	Ometab	Intas Pharmaceutical Ltd.	India	1.4	1.4	1.4	1.4	1.4	1.4	1.4	0.0	0.0	Pass	
B-108	B108/MM14/YG/	Ometab	Intas Pharmaceutical Ltd.	India	3.5	7.2	4.9	4.2	6.9	4.9	5.3	1.5	28.3	Pass	
PB-002	PB-002/MM14/YC	Ome-M	Rainbow Life Sciences Pvt. Ltd.	India	11.0	18.1	11.0	17.7	18.2	11.2	14.5	3.8	26.1	Fail	Fail
A-078	A078/MM14/YG/	Reloc-20	Rhydburg Pharmaceuticals Ltd.	India	23.0	34.4	17.1	23.3	33.1	16.6	24.6	7.6	31.1	Fail	Fail
A-011	A011/MM14/YG/	Omesec	The United Drug (1996) Co,Ltd.	Thailand	2.7	2.6	3.1	2.7	2.9	3.0	2.8	0.2	7.0	Pass	
A-091	A091/MM14/YG/	Omesec	The United Drug (1996) Co,Ltd.	Thailand	2.7	3.2	4.7	4.7	2.8	3.3	3.6	0.9	24.7	Pass	
B-059	B-059/MM14/YG,	Omesec	The United Drug(1996) Co., Ltd	Thailand	2.3	2.2	2.7	2.3	2.5	2.6	2.4	0.2	8.2	Pass	
A-097	A097/MM14/YG/	Omesafe	UNIVERSAL PHARMACEUTICALS LI	India	2.8	2.7	6.7	2.6	2.7	3.6	3.5	1.6	46.1	Pass	
B-049	B-049/MM14/YG,	Virom	Virchow Healthcare Drivate Limi	India	2.3	2.5	2.7	0.9	0.9	0.9	1.7	0.9	54.1	Pass	
B-015	B-015/MM14/YG,	HYCID	XL LABORATORIES PVT. LTD.	India	17.9	17.2	17.7	18.0	17.5	17.7	17.7	0.3	1.7	Fail	Fail
A-067	A067/MM14/YG/	HYCID	XL LABORATORIES PVT.LTD.	India	3.3	9.0	9.0	8.0	5.1	9.1	7.3	2.5	33.8	Pass	

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	Disso Final Initial Judge	Disso Final New Judge Q=65*0.8+ 5%=57	Disso New Final Judge
51.3	79.2	76.0	65.2	77.9	70.0	70.0	10.5	15.1	Fail	Fail	Pass	Fail
56.0	52.7	47.6	56.4	54.1	48.6	52.6	3.7	7.1	Fail	Fail	Fail	Fail
82.7	94.3	95.4	96.0	95.4	96.1	93.3	5.2	5.6	Pass	Pass		
92.8	95.2	98.8	97.5	97.3	94.7	96.0	2.2	2.3	Pass	Pass		
81.6	92.7	89.7	83.0	93.3	91.8	88.7	5.1	5.8	Pass	Pass		
96.0	92.6	95.2	91.6	94.0	95.8	94.2	1.8	1.9	Pass	Pass		
96.6	97.9	98.3	66.4	98.5	97.3	92.5	12.8	13.9	Pass	Pass		
82.7	94.3	93.5	94.2	95.4	95.7	92.7	4.9	5.3	Pass	Pass		
77.0	79.8	80.1	81.4	80.1	77.2	79.3	1.8	2.2	Pass	Pass		
83.1	84.9	82.2	82.7	83.6	82.1	83.1	1.0	1.2	Pass	pass		
96.9	99.5	98.2	96.1	96.4	98.4	97.6	1.3	1.4	Pass	pass		
86.9	72.9	75.2	76.9	75.4	86.8	79.0	6.2	7.9	Pass	Pass		
97.9	95.6	97.7	95.1	96.2	95.7	96.4	1.2	1.2	Pass	Pass		
99.3	98.1	98.6	95.4	99.0	98.0	98.1	1.4	1.4	Pass	Pass		
77.0	79.8	80.1	94.3	94.4	95.4	86.8	8.7	10.0	Pass	Pass		
52.1	53.8	47.6	51.8	50.9	48.5	50.8	2.3	4.6	Fail	Fail	Fail	Fail
85.4	84.1	83.3	81.7	85.2	83.6	83.9	1.3	1.6	Pass	Fail		Fail
49.5	49.7	63.4	55.7	50.7	50.7	53.3	5.5	10.2	Fail	Fail	Fail	Fail
53.6	62.8	62.1	52.8	53.4	62.6	57.9	5.1	8.8	Fail	Fail	Pass	Fail
30.7	34.4	26.5	54.9	71.2	57.6	45.9	17.9	39.0	Fail	Fail	Fail	Fail
54.7	72.7	57.1	31.1	34.2	27.9	46.3	17.9	38.7	Fail	Fail	Fail	Fail
70.3	67.7	73.1	72.3	77.4	74.8	72.6	3.4	4.7	Fail	Fail	Pass	Fail
50.2	47.5	80.7	58.6	68.2	56.9	60.4	12.3	20.4	Fail	Fail	Pass	Fail
78.3	70.7	78.4	69.3	68.3	66.6	71.9	5.1	7.1	Fail	Fail	Pass	Fail
31.4	32.1	35.5	31.8	73.9	73.2	46.3	21.2	45.7	Fail	Fail	Fail	Fail
49.7	47.1	79.3	48.8	77.9	77.0	63.3	16.2	25.6	Fail	Fail	Pass	Fail
60.1	65.2	61.7	60.1	65.1	61.7	62.3	2.3	3.7	Fail	Fail	Pass	Fail
73.8	79.3	71.4	72.4	71.1	70.8	73.1	3.9	5.4	Pass	pass		
56.6	70.7	55.2	54.5	48.1	74.7	60.0	10.4	17.3	Fail	Fail	Pass	Fail
73.9	77.7	62.1	75.0	60.7	60.8	68.4	8.0	11.6	Fail	Fail	Pass	Fail
75.3	75.8	60.7	73.7	63.2	74.1	70.5	6.7	9.5	Fail	Fail	Pass	Fail
76.8	68.0	70.6	76.9	71.1	76.5	73.3	3.9	5.3	Fail	Fail	Pass	Pass
72.5	72.1	67.3	67.6	73.4	72.5	70.9	2.7	3.8	Fail	Fail	Pass	Pass
77.6	69.5	77.7	55.7	66.9	53.7	66.9	10.4	15.5	Fail	Fail	Pass	Pass
69.0	73.1	66.6	71.7	67.5	72.5	70.1	2.8	3.9	Fail	Fail	Pass	Pass
18.3	19.5	17.9	18.5	18.9	18.3	18.6	0.6	3.0	Fail	Fail	Fail	Fail
69.4	67.9	75.2	67.4	67.6	72.5	70.0	3.2	4.5	Fail	Fail	Pass	Pass
80.0	74.7	91.1	80.0	76.4	90.3	82.1	7.0	8.5	Pass	pass		
99.6	98.6	98.8	97.7	97.4	94.6	97.8	1.8	1.8	Pass	Pass		
92.2	86.9	87.1	91.1	88.9	92.9	89.9	2.6	2.9	Pass	Pass		
67.6	81.2	79.8	80.6	68.5	68.2	74.3	6.8	9.2	Fail	Fail	Pass	Pass
71.7	94.3	86.6	73.1	93.9	86.8	84.4	9.9	11.7	Pass	Pass		
59.7	98.8	61.0	59.7	98.7	61.4	73.2	19.8	27.1	Fail	Fail	Pass	Fail
87.1	86.9	87.2	86.4	88.0	87.9	87.2	0.6	0.7	Pass	Pass		
92.2	87.5	87.3	91.2	88.4	92.3	89.8	2.3	2.6	Pass	Pass		
51.5	60.6	59.9	50.7	51.3	60.4	55.7	5.0	9.0	Fail	Fail	Fail	Fail
49.4	43.5	50.8	49.9	44.1	50.9	48.1	3.4	7.1	Fail	Fail	Fail	Fail
93.5	91.0	92.9	89.3	92.8	94.3	92.3	1.8	2.0	Pass	pass		
89.9	93.5	95.8	99.9	95.9	98.2	95.5	3.5	3.7	Pass	Pass		
93.9	97.7	99.8	93.3	93.4	91.2	94.9	3.2	3.4	Pass	Pass		
94.6	95.2	78.9	96.5	80.6	82.9	88.1	8.1	9.2	Pass	Pass		
66.4	85.3	84.9	65.6	83.7	66.3	75.4	10.2	13.5	Fail	Fail	Pass	Fail
39.7	38.5	42.8	39.8	38.9	42.6	40.4	1.9	4.6	Fail	Fail	Fail	Fail
82.2	71.8	73.5	86.2	70.2	76.3	76.7	6.3	8.2	Pass	Pass		

% of Quantity Capsule 1	% of Quantity capsule 2	% of Quantity Capsule 3	% of Quantity capsule 4	% of Quantity Capsule 5	% of Quantity capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Judge	New Judge 10% *1.2= 12% dissolved
10.2	8.7	3.0	8.9	8.7	10.5	10.3	4.4	42.4	Pass	
7.8	8.3	6.8	7.7	6.8	9.5	9.4	1.8	19.4	Pass	
33.7	31.6	34.5	34.8	35.5	39.3	24.0	11.5	47.9	Fail	Fail
25.0	25.8	22.1	26.5	27.9	32.4	25.5	2.8	11.1	Fail	Fail
7.0	6.5	8.8	4.3	6.9	8.4	9.8	3.6	36.4	Pass	
3.8	6.8	3.9	5.1	3.6	4.6	9.2	5.3	58.0	Pass	
8.8	10.7	9.1	10.0	8.2	12.8	7.3	4.0	55.2	Pass	
12.0	16.3	11.1	12.1	14.2	11.2	14.4	4.1	28.8	Fail	Fail
4.4	3.9	4.0	5.7	18.3	6.8	10.4	5.4	52.6	Pass	
1.3	5.6	6.8	4.1	4.5	3.8	8.4	4.8	57.0	Pass	
3.7	4.3	6.6	3.8	3.3	5.1	10.5	7.5	71.0	Fail	Pass
15.6	11.1	11.7	13.1	11.7	12.7	14.4	5.1	35.2	Fail	Fail
11.6	3.0	13.5	12.7	11.0	12.3	12.6	4.2	33.0	Fail	Fail
8.0	7.5	6.8	6.7	6.4	7.8	4.4	3.0	67.2	Pass	

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	Initial Judge	Disso Initial Final Judge	New Judge Q=52	Disso New Final Judge
63.5	71.2	102.5	64.7	76.4	46.9	70.4	14.3	20.3	Pass	Pass		
71.2	64.9	74.5	64.9	73.3	61.8	60.5	9.4	15.5	Fail	Fail	Pass	Pass
37.1	49.6	41.5	37.8	49.6	40.3	63.2	21.9	34.6	Fail	Fail	Pass	Fail
35.2	34.1	32.5	34.1	35.7	37.1	46.3	12.6	27.2	Fail	Fail	Fail	Fail
63.3	52.7	60.6	51.7	42.5	50.0	63.0	11.4	18.2	Fail	Fail	Pass	Pass
65.6	54.7	62.1	63.1	63.3	64.9	61.3	8.8	14.3	Fail	Fail	Pass	Pass
74.9	64.9	61.2	65.5	62.3	75.3	69.6	5.9	8.5	Pass	Pass		
34.0	27.7	31.1	32.4	28.6	26.2	46.6	20.7	44.3	Fail	Fail	Fail	Fail
58.8	81.4	72.6	67.6	73.9	64.5	64.9	10.2	15.7	Pass	Pass		
80.5	74.6	75.1	60.4	64.0	67.9	69.4	7.5	10.8	Pass	Pass		
67.2	52.1	62.3	79.2	65.7	76.5	68.8	8.2	12.0	Pass	Fail		Pass
38.4	71.2	56.3	41.9	38.2	69.0	62.9	15.2	24.1	Fail	Fail	Pass	Pass
60.6	41.1	48.6	52.5	64.5	50.4	61.9	11.1	18.0	Fail	Fail	Pass	Pass
69.8	61.6	66.0	53.7	60.9	68.5	65.1	8.3	12.7	Pass	Pass		
39.2	67.8	56.7	43.5	41.6	69.6	61.6	12.9	20.9	Fail	Fail	Pass	Pass
53.0	69.8	66.7	60.4	61.1	66.8	66.5	5.9	8.9	Pass	Pass		
61.7	78.7	77.4	71.1	81.4	81.0	74.8	6.9	9.2	Pass	Pass		
24.3	18.1	29.6	19.4	22.9	18.6	47.7	30.0	62.9	Fail	Fail	Fail	Fail
61.8	90.6	60.5	64.9	57.5	53.4	60.2	10.7	17.7	Fail	Fail	Pass	Fail
65.6	72.1	81.4	78.6	78.2	80.4	75.7	8.0	10.5	Pass	Pass		

% of Quantity Capsule 1	% of Quantity Capsule 2	% of Quantity Capsule 3	% of Quantity Capsule 4	% of Quantity Capsule 5	% of Quantity Capsule 6	% of Quantity Capsule 7	% of Quantity Capsule 8	% of Quantity Capsule 9	% of Quantity Capsule 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	AV (Acceptance Value)	Judge	New Judge AV=18	Mean % of Quantity	Judge	New Judge BP 76.0≦mean≦126
98.4	103.4	96.8	103.9	100.1	99.0	94.2	99.7	98.1	95.7	98.9	3.1	3.1	7.4	Pass		98.9	Pass	
90.5	91.9	91.6	95.1	95.2	96.6	91.0	90.8	91.1	96.5	93.0	2.5	2.7	11.5	Pass		93.0	Fail	Pass
88.2	87.8	86.7	97.1	83.7	84.2	88.3	93.3	85.2	105.7	90.0	6.9	7.6	25.0	Fail	Fail	90.0	Fail	Pass
99.9	103.1	98.4	102.9	105.9	94.3	102.8	101.5	98.1	103.8	101.1	3.4	3.4	8.2	Pass		101.1	Pass	
97.5	95.4	81.2	90.8	100.2	98.4	100.1	94.5	93.9	101.2	95.3	6.0	6.2	17.5	Fail	Pass	95.3	Pass	
99.1	108.0	100.1	99.8	99.6	106.5	103.0	100.4	104.1	107.9	102.9	3.6	3.5	7.2	Pass		102.9	Pass	
102.7	102.6	105.7	101.5	96.8	106.0	106.1	105.5	101.0	106.7	103.5	3.1	3.0	5.6	Pass		103.5	Pass	
95.9	94.0	97.5	91.8	91.4	90.8	99.0	100.9	96.1	104.8	96.2	4.5	4.7	13.0	Pass		96.2	Pass	
97.1	94.1	95.2	100.0	99.5	100.9	92.6	105.0	97.8	102.7	98.5	3.9	4.0	9.4	Pass		98.5	Pass	
107.7	105.9	104.9	101.8	99.9	104.6	103.2	104.3	107.8	105.1	104.5	2.4	2.3	2.8	Pass		104.5	Pass	
101.6	106.5	107.0	106.7	106.5	105.2	106.5	104.5	109.7	109.8	106.4	2.4	2.2	0.8	Pass		106.4	Fail	Pass
101.4	106.5	106.8	106.7	106.5	105.1	107.9	107.4	109.2	109.7	106.7	2.3	2.2	0.3	Pass		106.7	Fail	Pass
99.5	107.6	104.4	106.9	104.4	109.8	107.9	109.4	108.3	105.4	106.4	3.1	2.9	2.5	Pass		106.4	Fail	Pass
99.6	108.0	99.8	98.9	106.3	105.3	104.0	99.5	100.2	102.9	102.4	3.3	3.2	7.0	Pass		102.4	Pass	
99.8	107.9	104.5	107.2	104.5	109.8	107.8	109.6	108.4	105.8	106.5	3.0	2.8	2.2	Pass		106.5	Fail	Pass
91.1	91.6	92.7	97.9	99.0	97.1	94.9	96.7	93.7	93.8	94.9	2.7	2.9	10.2	Pass		94.9	Pass	
89.8	92.1	89.0	88.8	90.8	93.0	92.2	93.5	90.0	84.7	90.4	2.6	2.9	14.3	Pass		90.4	Fail	Pass
89.8	92.1	89.1	88.9	91.0	93.0	92.3	93.5	89.9	84.8	90.4	2.6	2.9	14.2	Pass		90.4	Fail	Pass
87.9	89.2	89.3	87.9	90.6	87.9	88.6	85.5	91.0	93.8	89.2	2.2	2.5	5.4	Pass		89.2	Fail	Pass
92.1	96.0	90.3	91.2	92.0	95.0	94.2	93.6	95.9	96.5	93.7	2.2	2.3	10.1	Pass		93.7	Fail	Pass
96.4	94.7	95.8	91.6	97.6	92.5	97.6	96.6	98.5	98.0	95.9	2.3	2.4	8.2	Pass		95.9	Pass	
102.0	95.8	110.0	107.2	107.8	108.5	106.7	98.2	105.6	105.3	104.7	4.6	4.4	7.9	Pass		104.7	Pass	
90.7	95.5	93.6	91.0	99.3	90.8	96.0	91.3	98.0	91.7	93.8	3.2	3.4	12.4	Pass		93.8	Fail	Pass
96.2	97.8	99.7	95.8	98.9	94.6	93.0	93.6	98.6	90.6	95.9	2.9	3.1	9.7	Pass		95.9	Pass	
93.5	94.2	102.0	93.3	96.1	93.1	98.5	100.9	92.9	93.8	95.8	3.4	3.6	10.9	Pass		95.8	Pass	
98.9	93.0	95.9	96.4	100.3	99.5	92.0	96.3	100.5	103.6	97.6	3.6	3.7	9.5	Pass		97.6	Pass	
96.3	101.6	92.5	98.5	99.4	96.6	97.9	96.6	100.0	98.2	97.8	2.5	2.5	6.7	Pass		97.8	Pass	
101.2	94.0	105.6	98.6	101.9	98.5	95.0	95.6	102.6	102.7	99.6	3.8	3.9	8.2	Pass		99.6	Pass	
90.0	90.9	92.3	92.2	95.9	95.4	92.5	94.4	93.4	92.2	92.9	1.9	2.0	10.1	Pass		92.9	Fail	Pass
93.2	98.1	96.6	99.7	95.5	94.3	97.0	97.2	96.9	101.7	97.0	2.5	2.5	7.4	Pass		97.0	Pass	
90.1	95.5	92.5	95.0	96.7	103.7	98.3	90.8	95.4	97.0	95.5	3.9	4.1	12.4	Pass		95.5	Pass	
92.1	102.4	99.3	96.7	92.8	98.1	95.1	100.4	98.0	98.5	97.3	3.3	3.4	9.0	Pass		97.3	Pass	
92.3	94.7	98.9	100.1	99.6	95.7	93.9	95.3	92.7	97.2	96.0	2.8	2.9	9.1	Pass		96.0	Pass	
95.2	90.3	96.8	103.7	95.0	92.6	98.2	90.7	95.9	97.1	95.5	3.9	4.1	12.4	Pass		95.5	Pass	
92.5	92.6	96.1	92.2	92.3	90.0	91.1	93.6	94.5	95.4	93.0	1.9	2.0	10.0	Pass		93.0	Fail	Pass
94.8	92.6	97.8	98.2	97.0	92.0	98.3	96.7	99.3	96.0	96.3	2.5	2.6	8.2	Pass		96.3	Pass	
97.1	93.7	96.7	97.7	94.0	93.4	94.0	96.9	91.6	93.9	94.9	2.0	2.1	8.5	Pass		94.9	Pass	
56.5	47.1	95.7	99.2	77.9	47.6	83.0	72.5	85.2	99.6	76.4	20.1	26.4	70.4	Fail	Fail	76.4	Fail	Pass
89.0	91.5	96.7	95.8	98.8	100.1	88.1	90.3	93.3	92.7	93.6	4.1	4.4	14.7	Pass		93.6	Fail	Pass
92.4	93.0	94.0	99.5	100.6	98.6	96.3	98.2	94.8	95.2	96.3	2.8	3.0	9.1	Pass		96.3	Pass	
75.6	84.7	81.9	86.5	101.0	80.1	99.1	100.1	95.9	91.3	89.6	9.1	10.2	30.8	Fail	Fail	89.6	Fail	Pass
93.0	78.3	77.4	76.2	89.1	94.1	91.4	97.8	82.9	87.6	86.8	7.7	8.8	30.1	Fail	Fail	86.8	Fail	Pass
109.2	107.2	107.9	106.3	102.1	105.1	104.5	105.3	106.4	100.3	105.4	2.7	2.5	2.4	Pass		105.4	Pass	
86.1	91.8	87.7	83.8	90.4	86.5	88.2	89.4	84.2	90.7	87.9	2.7	3.1	17.2	Fail	Pass	87.9	Fail	Pass
101.2	101.4	98.2	99.3	96.9	96.9	98.6	96.0	99.1	101.5	98.9	2.0	2.0	4.7	Pass		98.9	Pass	
90.9	81.7	99.9	92.7	93.5	85.0	85.6	87.3	85.5	86.5	88.8	5.4	6.0	22.5	Fail	Fail	88.8	Fail	Pass
99.8	94.0	62.2	62.5	76.6	45.5	73.8	90.3	76.0	78.7	75.9	16.4	21.5	61.8	Fail	Fail	75.9	Fail	Fail
100.0	93.9	99.7	95.4	96.7	97.9	98.4	98.9	104.0	103.3	98.8	3.2	3.2	7.6	Pass		98.8	Pass	
93.3	94.5	96.5	91.2	96.4	95.7	93.8	92.6	98.3	98.7	95.1	2.4	2.6	9.3	Pass		95.1	Pass	
98.3	90.0	97.8	90.3	99.0	101.3	101.6	104.2	103.4	103.3	98.9	5.1	5.2	12.2	Pass		98.9	Pass	
94.1	103.4	99.3	101.9	96.4	104.2	97.3	103.5	98.6	104.0	100.3	3.6	3.6	8.7	Pass		100.3	Pass	
80.6	69.2	77.8	80.0	89.5	78.4	85.0	85.6	82.6	83.4	81.2	5.5	6.8	30.5	Fail	Fail	81.2	Fail	Pass
98.6	113.1	90.3	98.3	116.2	96.6	100.7	108.9	113.3	113.5	104.9	9.1	8.6	18.3	Fail	Fail	104.9	Pass	
88.1	99.5	100.1	94.7	95.0	89.9	98.0	87.3	90.8	91.6	93.5	4.7	5.0	16.2	Fail	Pass	93.5	Fail	Pass

AV (Acceptance Value)	Judge	New Judge AV= 18	Kanazawa Univ. Quantity test (10 caps)	Judge	New Judge	DS Final Judge	DS New Final Judge	All test pass or any fail	New All test pass or any fail
7.4	Pass		98.9	Pass		Pass		Pass	
11.5	Pass		93.0	Fail	Pass	Fail	Pass	Fail	Fail
19.9	Fail	Fail	90.0	Fail	Pass	Pass		Fail	Fail
8.2	Pass		101.1	Pass		Pass		Pass	
17.5	Pass		95.3	Pass		Pass		Pass	
7.2	Pass		102.9	Pass		Pass		Pass	
5.6	Pass		103.5	Pass		Pass		Pass	
13.0	Pass		96.2	Pass		Pass		Pass	
9.4	Pass		98.5	Pass		Pass		Pass	
2.8	Pass		104.5	Pass		Pass		Pass	
0.8	Pass		106.4	Fail	Pass	Pass		Fail	Pass
0.3	Pass		106.7	Fail	Pass	Pass		Fail	Pass
2.5	Pass		106.4	Fail	Pass	Pass		Fail	Pass
7.0	Pass		102.4	Pass		Pass		Pass	
2.2	Pass		106.5	Fail	Pass	Pass		Fail	Pass
10.2	Pass		94.9	Pass		Fail	Fail	Fail	Fail
14.3	Pass		90.4	Fail	Pass	Fail	Fail	Fail	Fail
14.2	Pass		90.4	Fail	Pass	Fail	Fail	Fail	Fail
5.4	Pass		89.2	Fail	Pass	Fail	Fail	Fail	Fail
10.1	Pass		93.7	Fail	Pass	Fail	Fail	Fail	Fail
8.2	Pass		95.9	Pass		Fail	Fail	Fail	Fail
7.9	Pass		104.7	Pass		Pass		Pass	
12.4	Pass		93.8	Fail	Pass	Pass		Fail	Pass
9.7	Pass		95.9	Pass		Pass		Pass	
10.9	Pass		95.8	Pass		Fail	Fail	Fail	Fail
9.5	Pass		97.6	Pass		Fail	Fail	Fail	Fail
6.7	Pass		97.8	Pass		Fail	Fail	Fail	Fail
8.2	Pass		99.6	Pass		Pass		Pass	
10.1	Pass		92.9	Fail	Pass	Pass		Fail	Pass
7.4	Pass		97.0	Pass		Pass		Pass	
12.4	Pass		95.5	Pass		Pass		Pass	
9.0	Pass		97.3	Pass		Fail	Pass	Fail	Pass
9.1	Pass		96.0	Pass		Pass		Pass	
12.4	Pass		95.5	Pass		Pass		Pass	
10.0	Pass		93.0	Fail	Pass	Fail	Pass	Fail	Pass
8.2	Pass		96.3	Pass		Fail	Fail	Fail	Fail
8.5	Pass		94.9	Pass		Pass		Pass	
70.4	Fail	Fail	76.4	Fail	Pass	Pass		Fail	Pass
14.7	Pass		93.6	Fail	Pass	Pass		Fail	Pass
9.1	Pass		96.3	Pass		Pass		Pass	
20.8	Fail	Fail	89.6	Fail	Pass	Pass		Fail	Fail
21.6	Fail	Fail	86.8	Fail	Pass	Pass		Fail	Fail
2.4	Pass		105.4	Pass		Fail	Fail	Fail	Fail
13.8	Pass		87.9	Fail	Pass	Pass		Fail	Pass
4.7	Pass		98.9	Pass		Pass		Pass	
16.7	Fail	Pass	88.8	Fail	Pass	Fail	Fail	Fail	Fail
61.8	Fail	Fail	75.9	Fail	Fail	Fail	Fail	Fail	Fail
7.6	Pass		98.8	Pass		Pass		Pass	
9.3	Pass		95.1	Pass		Pass		Pass	
12.2	Pass		98.9	Pass		Pass		Pass	
8.7	Pass		100.3	Pass		Pass		Pass	
30.5	Fail	Fail	81.2	Fail	Pass	Pass		Fail	Fail
10.4	Pass		104.9	Pass		Fail	Fail	Fail	Fail
13.6	Pass		93.5	Fail	Pass	Pass		Fail	Pass

Omeprazole USP

Kanazawa Univ. Dissolution test USP. Buffer Stage– No unit is less than Q+5% (Q=75%)												considered Q=65%	
89.4	87.9	90.5	92.6	92.2	89.5	90.3	1.8	2.0	Pass	Pass			
90.7	85.0	90.3	89.7	90.1	91.9	89.6	2.4	2.7	Pass	Pass			
86.1	95.4	95.7	96.3	88.0	93.2	92.4	4.3	4.7	Pass	Pass			
92.8	97.9	93.9	90.9	92.7	97.6	94.3	2.9	3.0	Pass	Pass			
77.1	81.7	80.0	78.6	81.4	77.7	79.4	1.9	2.4	Fail	Fail	Pass	Pass	
83.4	89.1	86.9	88.0	85.5	88.4	86.9	2.1	2.5	Pass	Pass			
88.4	89.2	86.4	87.5	93.3	87.8	88.8	2.4	2.7	Pass	Pass			
85.6	89.2	86.5	87.5	90.0	87.6	87.7	1.6	1.9	Pass	Pass			
89.4	90.4	99.5	91.6	92.2	96.4	93.2	3.9	4.2	Pass	Pass			
88.8	89.9	98.9	91.0	91.7	95.9	92.7	3.9	4.2	Pass	Pass			
81.2	77.6	80.0	78.6	77.3	75.9	78.4	1.9	2.5	Fail	Fail	Pass	Fail	

Kanazawa Univ. Content uniformity test (1st stage)							tolerance: AV≦15.0									USP 90.0≦mean≦110		USP 76.0≦mean≦132	
106.7	105.7	103.3	107.9	105.9	97.6	104.6	94.6	103.2	104.0	103.4	4.1	4.0	8.1	Pass		103.4	Pass		
105.1	104.8	106.7	104.0	108.5	103.9	108.2	107.7	105.3	105.7	106.0	1.7	1.6	9.3	Pass		106.0	Pass		
93.7	98.7	97.3	93.1	102.3	101.1	92.4	93.3	90.7	107.7	97.0	5.4	5.6	14.4	Pass		97.0	Pass		
102.2	96.2	110.0	107.4	107.9	108.5	106.8	98.5	103.9	105.3	104.7	4.5	4.3	7.7	Pass		104.7	Pass		
88.9	63.0	70.3	62.4	86.7	84.7	70.0	70.9	95.3	91.9	78.4	12.3	15.7	49.7	Fail	Fail	78.4	Fail	Pass	
109.7	108.2	109.3	100.4	108.1	109.8	106.6	102.4	107.7	107.6	107.0	3.2	2.9	2.1	Pass		107.0	Pass		
98.0	92.7	99.3	100.4	105.5	90.2	96.2	101.2	101.2	93.3	97.8	4.7	4.8	11.9	Pass		97.8	Pass		
97.1	93.1	100.6	106.6	99.6	98.8	93.2	98.1	104.6	93.3	98.5	4.7	4.7	11.2	Pass		98.5	Pass		
90.1	104.8	101.3	101.7	97.1	108.1	100.5	102.6	99.5	103.5	100.9	4.8	4.8	11.6	Pass		100.9	Pass		
100.0	94.7	101.4	102.5	107.7	92.1	98.3	103.3	103.3	95.2	99.9	4.8	4.8	11.5	Pass		99.9	Pass		
93.4	106.4	98.1	93.7	103.5	94.4	91.0	95.3	94.7	105.6	97.6	5.5	5.7	14.2	Pass		97.6	Pass		

Ceftriaxone

Serial N	Sample Code	Trade name of	Name of Manuf	Manufacturi	% of Quantity Vial1	% of Quantity Vial 2	% of Quantity Vial 3	% of Quantity Vial 4	% of Quantity Vial 5	% of Quantity Vial 6	% of Quantity Vial 7	% of Quantity Vial 8	% of Quantity Vial 9	% of Quantity Vial 10	Mean % of Quantity	% of Quantity SD	% of Quantity %CV	QTY Judge	New QTY Judge
A-010	A010/MM14/YG/01/H	BECEF	Nectar Lifescie	India	124.43	122.277	117.405	111.121	122.58	119.109	115.877	111.927	119.555	112.343	117.7	4.7631335	4.0481356	Fail	Pass
A-028	A028/MM14/YG/04/C	TEFAXONE	Stallion LABOI	India	102.6	102.6	103.4	105.3	104.2	104.1	101.2	103.0	103.5	103.0	103.3	1.1204033	1.0847109	Pass	
A-047	A047/MM14/YG/05/C	TRAXONE	Korea Pharma	Korea	107.8	108.2	109.4	107.9	105.1	108.6	106.3	108.6	109.0	108.6	108.0	1.301357	1.2052883	Pass	
A-062	A062/MM14/YG/01/O	LYFAXONE	LYKA LABS LIMI	India	111.0	110.2	112.2	113.9	115.4	111.1	115.0	110.3	111.4	110.3	112.1	1.9964575	1.7812202	Pass	
A-087	A087/MM14/YG/01/W	Ceftron	SQUARE PHARI	Bangladesl	106.5	104.4	106.2	108.2	105.9	109.3	107.5	109.5	105.8	109.5	107.3	1.7882748	1.6670657	Pass	
A-093	A093/MM14/YG/03/W	DALITRIXON	SHENZHEN ZHI	China	107.8	108.6	108.8	108.2	110.6	110.6	110.3	105.4	109.5	105.4	108.5	1.9207722	1.7702399	Pass	
A-094	A094/MM14/YG/03/W	TRAXEF	CCL Pharmace	Pakistan	108.8	108.3	108.7	108.9	108.3	107.7	107.8	108.8	110.9	108.8	108.7	0.8792508	0.8088747	Pass	
B-014	B-014/MM14/YG/04/C	C-Tri	Emcure PHARM	India	108.6	109.9	108.3	109.1	107.7	107.4	109.1	107.7	108.6	107.7	108.4	0.8211277	0.7574986	Pass	
B-020	B-020/MM14/YG/05/C	UTRIXONE	UMEDICA LABO	India	106.5	105.2	106.2	103.7	104.6	106.2	109.2	109.8	107.0	109.8	106.8	2.1423105	2.0056308	Pass	
B-041	B-041/MM14/YG/01/H	POWERCEF	WOCKHARDT L	India	105.7	106.0	109.9	106.6	103.9	105.9	103.7	107.6	105.2	107.6	106.2	1.8691588	1.7599819	Pass	
B-082	B-082/MM14/YG/01/C	ZEFONE	Cadila Health	India	109.2	108.5	109.4	108.2	109.1	105.6	106.0	107.7	108.5	107.7	108.0	1.2988663	1.2027108	Pass	
PA-007	PA007/MM14/YG/01/I	Oframax	RANBAXY LABO	India	108.7	109.0	108.3	108.2	108.5	108.9	107.7	108.0	110.3	108.0	108.5	0.7328835	0.675193	Pass	
A-031	A031/MM14/YG/01/O	PARCEF	Jayson Pharm	Bangladesl	89.34	139.89	135..054	124.33	117.37	121.08	107.18	122.08	124.42	121.78	118.6	13.860013	11.685618	Fail	Pass
A-098	A098/MM14/YG/01/H	CEFTRIAXON	M.J.BIOPHARM	India	106.39	113.20	109.84	114.41	112.13	111.64	110.36	108.79	109.40	110.76	110.7	2.3030828	2.0806339	Pass	
B-021	B-021/MM14/YG/05/C	CEFDEC	BELCO PHARM	India	106.65	110.03	111.10	106.70	107.92	108.31	105.68	107.16	105.24	107.51	107.6	1.8231694	1.6939404	Pass	
B-025	B-025/MM14/YG/06/C	Ceftriaxone	Myanma Pharı	Myanmar	106.55	105.70	109.19	105.16	104.43	109.46	113.24	113.02	103.04	102.31	107.2	3.875495	3.6148768	Pass	
B-033	B-033/MM14/YG/01/H	Rocephin	F.Hoffmann-La	Switzland	111.40	109.24	112.44	111.26	110.71	114.94	111.58	115.00	109.41	109.91	111.6	2.0431297	1.8309534	Pass	
A-055	A055/MM14/YG/01/H	Oframax	RANBAXY LABO	India	114.68	103.49	104.38	103.70	104.15	104.08	103.53	105.26	107.14	105.26	105.6	3.3886221	3.2099285	Pass	
B-097	B-097/MM14/YG/02/C	BECEF	Nectar Lifescie	India	113.50	113.38	113.42	114.97	115.92	114.78	115.17	113.23	113.86	113.23	114.1	0.9770122	0.8559388	Pass	
A-027	A027/MM14/YG/04/C	BECEF	Nectar Lifescie	India	106.35	109.31	104.98	102.93	105.69	108.25	106.14	108.87	104.40	104.51	106.1	2.0958745	1.9746004	Pass	
A-029	A029/MM14/YG/04/C	LYFAXONE	LYKA LABS LIMI	India	108.98	103.90	107.80	101.91	102.47	109.30	105.43	107.81	105.95	101.11	105.5	3.0044357	2.8487271	Pass	
A-051	A051/MM14/YG/01/H	Oframax	RANBAXY LABO	India	111.91	105.87	104.91	104.09	105.81	105.61	103.08	110.40	107.50	108.68	106.8	2.8104251	2.6318637	Pass	
A-110	A110/MM14/YG/01/C	Trixone	TOQURE Pharı	India	104.25	97.81	101.04	99.92	106.75	101.00	103.82	101.96	105.13	103.37	102.5	2.6651732	2.6000647	Pass	
B-010	B-010/MM14/YG/02/C	Cefaxone	LUPIN LTD.	India	109.63	104.08	103.56	106.66	109.69	104.92	103.62	104.70	106.78	104.55	105.8	2.3035502	2.1768777	Pass	
A-008	A008/MM14/YG/01/H	Oframax	RANBAXY LABO	India	110.31	107.77	108.26	107.07	108.79	107.31	108.13	108.93	107.37	110.81	108.5	1.2629433	1.1642606	Pass	
A-009	A009/MM14/YG/01/H	CEFTRIAXON	M.J.BIOPHARM	India	105.85	107.98	105.72	108.70	102.81	101.20	104.49	106.38	102.49	104.89	105.1	2.3905065	2.2755675	Pass	
A-032	A032/MM14/YG/03/C	UTRIXONE	UMEDICA LABO	India	108.28	111.14	105.56	108.08	108.21	109.42	105.26	104.61	105.13	103.78	106.9	2.4015438	2.2455772	Pass	
A-045	A045/MM14/YG/04/C	Ceftriaxone	Myanmar Phar	Myanmar	96.26	96.03	105.16	101.32	101.42	99.78	99.51	105.68	103.21	101.37	101.0	3.2557728	3.2243808	Pass	
A-046	A046/MM14/YG/05/C	C-Tri	Emcure PHARM	India	110.51	111.25	113.27	114.43	110.83	110.24	113.82	112.08	111.77	109.20	111.7	1.6766657	1.5005156	Pass	
A-056	A056/MM14/YG/01/H	BECEF	Nectar Lifescie	India	108.18	112.41	108.56	110.26	109.53	110.00	111.65	110.55	110.44	111.12	110.3	1.2998492	1.178793	Pass	
A-073	B-073/MM14/YG/01/H	POWERCEF	WOCKHARDT L	India	107.90	109.01	108.50	111.99	111.01	110.76	110.67	107.67	107.91	109.79	109.5	1.5341904	1.4008147	Pass	
A-081	A081/MM14/YG/02/H	LYFAXONE	LYKA LABS LIMI	India	106.00	102.23	104.36	109.30	106.48	110.40	108.38	105.97	104.48	105.96	106.4	2.4501827	2.3037993	Pass	
A-082	A082/MM14/YG/02/H	Oframax	RANBAXY LABO	India	103.21	107.15	111.10	106.50	108.35	105.71	103.68	112.17	106.11	111.17	107.5	3.1308773	2.9120295	Pass	
A-103	A103/MM14/YG/02/H	BECEF	Nectar Lifescie	India	108.10	105.28	110.35	104.52	110.46	105.80	106.02	106.84	106.12	107.00	107.0	2.0181697	1.8853136	Pass	
A-109	A109/MM14/YG/01/C	BECEF	Nectar Lifescie	India	111.31	113.98	112.48	113.15	112.38	109.38	109.94	109.62	108.23	110.86	111.1	1.8530369	1.6674377	Pass	
A-013	A013/MM14/YG/01/H	LYFAXONE	LYKA LABS LIMI	India	94.63	102.90	96.61	98.98	97.82	103.60	92.65	96.80	100.11	95.75	98.0	3.4824192	3.5541425	Pass	
B-024	B-024/MM14/YG/06/C	Ceftriaxone	Myanma Pharı	Myanmar	102.71	98.63	104.18	103.42	102.42	103.75	105.73	102.97	102.37	112.55	103.9	3.5430774	3.4109775	Pass	
B-032	B-032/MM14/YG/01/H	Oframax	RANBAXY LABA	India	110.28	104.87	106.17	106.59	105.97	106.34	108.70	107.96	105.27	107.96	107.0	1.6789096	1.568919	Pass	
B-039	B-039/MM14/YG/01/H	Oframax	RANBAXY LABA	India	106.22	109.23	110.80	106.04	107.99	105.95	106.38	109.92	104.93	105.62	107.3	2.0330108	1.8945442	Pass	
B-055	B-055/MM14/YG/01/H	BECEF	Nectar Lifescie	India	101.25	101.43	100.30	100.81	105.88	99.54	99.47	102.22	102.02	106.88	102.0	2.507431	2.4587205	Pass	
B-056	B-056/MM14/YG/01/H	Oframax	RANBAXY LABA	India	110.41	110.13	111.47	105.49	105.83	107.83	105.51	109.49	106.90	108.44	108.1	2.18673	2.0219736	Pass	
B-057	B-057/MM14/YG/01/H	ZEFONE	Cadila Health	India	111.36	106.88	107.80	109.84	104.50	108.12	106.75	106.56	108.64	115.63	108.6	3.106839	2.8605828	Pass	
B-061	B-061/MM14/YG/01/C	LYFAXONE	LYKA LABS LIMI	India	106.00	105.14	105.92	107.70	105.27	107.78	107.32	105.02	105.71	106.73	106.3	1.0525429	0.9905438	Pass	
B-062	B-062/MM14/YG/01/C	Oframax	RANBAXY LABA	India	106.32	107.39	108.88	104.83	108.49	108.77	109.36	107.41	103.07	106.87	107.1	1.9777604	1.8459934	Pass	
B-073	B-073/MM14/YG/01/H	POWERCEF	WOCKHARDT L	India	101.75	100.85	100.83	100.81	99.60	98.52	96.52	101.97	97.38	99.22	99.7	1.8352227	1.839889	Pass	
B-083	B-083/MM14/YG/01/C	BECEF	Nectar Lifescie	India	107.99	107.29	104.44	103.85	108.00	105.91	108.69	104.77	105.71	108.60	106.5	1.8121895	1.7011966	Pass	
B-087	B-087/MM14/YG/04/V	TRAXONE	Korea Pharma	Korea	98.19	97.05	98.98	100.26	103.23	99.78	100.37	104.65	102.74	104.84	101.0	2.7091045	2.6820334	Pass	
B-103	B-103/MM14/YG/01/H	Oframax	RANBAXY LABA	India	107.53	106.38	108.51	109.16	109.26	109.78	111.26	109.71	110.73	6.75	98.9	32.412876	32.770953	Pass	
B-112	B-112/MM14/YG/05/C	Oframax	RANBAXY LABA	India	99.98	99.91	105.18	101.63	95.14	103.85	102.05	98.52	102.12	99.73	100.8	2.8335197	2.8107222	Pass	
*B-103	B-103/MM14/YG/01/H	Oframax	RANBAXY LABA	India	102.7	108.6	105.1	104.4	102.5	105.8	104.2	108.7	107.0	112.1	106.1	3.0	2.8	Pass	

AV (Acceptance Value)	CU Judge	CU Judge	AV (Acceptance Value)	CU Judge	New CU Judge	Kanazawa Univ. Quantity test (10 Vial	Judge	New Judge	New All Fail Judge
27.63	Fail	Fail	27.63	Fail	Fail	117.66	Fail	Pass	Fail
4.49	Pass		4.49	Pass		103.29	Pass		
9.62	Pass		9.62	Pass		107.97	Pass		
15.00	Pass		15.00	Pass		112.08	Pass		
10.10	Pass		10.10	Pass		107.27	Pass		
11.61	Pass		11.61	Pass		108.50	Pass		
9.31	Pass		9.31	Pass		108.70	Pass		
8.87	Pass		8.87	Pass		108.40	Pass		
10.34	Pass		10.34	Pass		106.81	Pass		
10.19	Pass		10.19	Pass		106.20	Pass		
9.62	Pass		9.62	Pass		107.99	Pass		
8.75	Pass		8.75	Pass		108.54	Pass		
50.36	Fail	Fail	50.36	Fail	Fail	118.61	Fail	Pass	Fail
14.72	Pass		14.72	Pass		110.69	Pass		
10.46	Pass		10.46	Pass		107.63	Pass		
15.00	Pass		15.00	Pass		107.21	Pass		
15.00	Pass		15.00	Pass		111.59	Pass		
12.23	Pass		12.23	Pass		105.57	Pass		
14.95	Pass		14.95	Pass		114.15	Pass		
9.64	Pass		9.64	Pass		106.14	Pass		
11.10	Pass		11.10	Pass		105.47	Pass		
12.53	Pass		12.53	Pass		106.78	Pass		
7.41	Pass		7.41	Pass		102.50	Pass		
9.82	Pass		9.82	Pass		105.82	Pass		
10.02	Pass		10.02	Pass		108.48	Pass		
9.34	Pass		9.34	Pass		105.05	Pass		
11.06	Pass		11.06	Pass		106.95	Pass		
6.16	Pass		6.16	Pass		100.97	Pass		
14.23	Pass		14.23	Pass		111.74	Pass		
11.92	Pass		11.92	Pass		110.27	Pass		
11.96	Pass		11.96	Pass		109.52	Pass		
10.78	Pass		10.78	Pass		106.35	Pass		
12.41	Pass		12.41	Pass		107.52	Pass		
10.34	Pass		10.34	Pass		107.05	Pass		
14.04	Pass		14.04	Pass		111.13	Pass		
8.85	Pass		8.85	Pass		97.98	Pass		
10.90	Pass		10.90	Pass		103.87	Pass		
9.53	Pass		9.53	Pass		107.01	Pass		
10.37	Pass		10.37	Pass		107.31	Pass		
6.52	Pass		6.52	Pass		101.98	Pass		
11.14	Pass		11.14	Pass		108.15	Pass		
14.55	Pass		14.55	Pass		108.61	Pass		
7.76	Pass		7.76	Pass		106.26	Pass		
10.25	Pass		10.25	Pass		107.14	Pass		
5.44	Pass		5.44	Pass		99.75	Pass		
9.35	Pass		9.35	Pass		106.52	Pass		
6.50	Pass		6.50	Pass		101.01	Pass		
77.79	Fail	Fail	77.79	Fail	Fail	98.91	Pass		Fail
6.80	Pass		6.80	Pass		100.81	Pass		
11.8	Pass								

Annex 2.1 Map of Cambodia