A Study on the Quality of Medicines in Community Pharmacies in Riyadh, Saudi Arabia

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Dissertation

A Study on the Quality of Medicines
in Community Pharmacies
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Dedication

To my beloved mother,

the soul of my great father,

and my beloved family…

Acknowledgments

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Adherence of Community Pharmacies in Riyadh, Saudi Arabia, to Optimal
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List of Abbreviations

Amox	Amoxicillin
AV	Acceptance Value
BP	British Pharmacopeia
CD	Compact Disc
Cefd	Cefadroxil
GPP	Good Pharmacy Practice
HPLC	High-Performance Liquid Chromatography
KSA	Kingdom of Saudi Arabia
LQAS	Lot Quality Assurance Sampling
MOH	Ministry of Health
MS	Microsoft
OTC	Over-the-Counter
PTP/SP	Push-Through Package/Strip Package
RS	Reference Standard
SFDA	Saudi Food and Drug Authority
STD	Standard
USA	United States of America
WHO	World Health Organization
USP	United States Pharmacopeia
USPRS	United States Pharmacopeia Reference Standard

Abstract

Poor-quality medicines are real threats to individuals and health systems worldwide. In developing countries, life-saving medicines, such as antibiotics, are the main target of counterfeiters. Substandard medicines are extremely prevalent due to poor manufacturing, distribution, and/or storage conditions. Data on the quality of medicines in Arab countries are very limited. This thesis is divided into two major parts.

The first part investigated the quality of amoxicillin capsules and tablets sold in community pharmacies (CPs) in Riyadh, Saudi Arabia, as an indicator of the quality of medicines sold in them. It estimated the proportion of pharmacies that were selling poor-quality medicines relative to a predetermined threshold (20%). It also field tested an economical sampling method for classifying the CPs according to the quality of their medicines in order to help decision makers with resource allocation.

Sampling was performed with the "mystery shopper" technique in 72 randomly selected CPs in Riyadh. The number of pharmacies for inclusion was calculated with Lot Quality Assurance Sampling (LQAS) method. The initial 1367 pharmacies were divided into two lots: chain and independent pharmacies (869 and 498, respectively). From each lot, 36 pharmacies were randomly selected, and 80 dosage units of a randomly selected amoxicillin brand were purchased from each selected pharmacy. If this brand was from more than one batch, the batches were considered different samples purchased from the same pharmacy. If samples from the same batch were purchased from different pharmacies, the samples were also considered different. The samples were checked for authenticity and analyzed for their drug content and content uniformity (CU) according to the United States Pharmacopeia (USP) by a validated high-performance liquid chromatographic (HPLC) method. If a sample from a pharmacy was found to be of poor quality, that pharmacy was considered a failed

pharmacy. If the number of failed pharmacies exceeded a predetermined decision value (three) in any lot, the lot was rejected and the proportion of pharmacies selling poor-quality amoxicillin was classified as higher than the predetermined threshold.

A total of 83 samples from 72 pharmacies were collected and analyzed (41 samples from chain pharmacies and 42 from independent pharmacies). The samples were found to be authentic, but 9 were substandard because they failed the CU test, with 6 of the 9 averaging less than 90% of the labeled content (the lowest was 80.7%). The content of the approved samples ranged from 90.6% to 104.2%. Certain batches passed the test in certain pharmacies and failed in others, indicating a possible degradation. The 9 failed samples were purchased from 4 chain and 5 independent pharmacies. Both lots were rejected because the predetermined decision value was exceeded, indicating that more than 20% of the pharmacies in each lot were selling poor-quality amoxicillin.

A problem existed with the quality of an essential drug in Riyadh's CPs. Exposure to excessive temperature during distribution or storage has unfavorable consequences on the quality of medicines, particularly in hot climates. This could be one of the possible reasons behind the existence of substandard amoxicillin in Riyadh's CPs. However, inefficient quality control at the manufacturing stage cannot be excluded.

The second part of the thesis explored the conditions under which medicines were kept in a random sample of 181 CPs in Riyadh. The pharmacist in charge in each pharmacy was interviewed and observations about the quality of storage were recorded.

The inspection revealed that in 9% of the CPs the readings of the existing room thermometers were more than 25 °C, and that 13% of the CPs lacked thermometers. Also in 33% of the CPs the readings of the refrigerator thermometers were outside the accepted range, and 7% of the CPs lacked refrigerator thermometers. About 15% of pharmacists were not informed about the local regulations of community pharmacy

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practice, neither before nor after taking up their current positions. Surprisingly, incorrect answers to simple questions about the system were frequently given by the informed pharmacists. Certain aspects of substandard storage conditions existed, in varying degrees, in significant percentages of pharmacies regardless of the pharmacists' qualifications, experience, or awareness about the local regulations of community pharmacy practice.

Stricter monitoring of the supply chain in Riyadh is necessary. More studies to monitor the quality of medicines and pharmacies are recommended, together with improvements in the education of pharmacists and distributors about the importance of adhering to optimal conditions of keeping and selling medicines.

Reference Theses

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H. Khojah, H. Pallos, N. Yoshida, M. Akazawa, H. Tsuboi and K. Kimura, "The Quality of Medicines in Community Pharmacies in Riyadh, Saudi Arabia: A Lot Quality Assurance Sampling (LQAS)-Based Survey." Accepted for publication in Pharmacology & Pharmacy Journal, Scientific Research Open Access, August 2013.

Chapter 1

The Quality of Amoxicillin Capsules and Tablets in Community Pharmacies in Riyadh, Saudi Arabia: A Lot Quality Assurance Sampling (LQAS) Survey

Background

Poor-quality medicines could be counterfeit or substandard. Counterfeit medicines are "deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging".[1] In contrast, substandard medicines are "genuine medicines produced by legitimate manufacturers that do not meet the quality specifications that the producer says they meet. For example, they may contain less (or more) active ingredient than written on the package. This may not be an intention to cheat, but may be due to problems with the manufacturing process".[2] Degraded medicines may be considered substandard, although they were originally genuine and of good quality. These medicines show deterioration subsequent to their expiration date or deterioration due to exposure to harsh environmental conditions during distribution and/or storage.[3,4]

The use of poor-quality medicines, especially counterfeits, may lead to a wide variety of health risks, including therapeutic failure, toxicity, bacterial resistance, and even death.[5] Moreover, the economic consequences of this situation are undesirable. Furthermore, people may lose their trust in health systems.[6]

Counterfeit medicines have become a global issue because of the continuing growth in the market for these products and because of the consequences of their use.[7] Although developing countries are the principal target of counterfeiters,[8,9] developed countries face many of the same risks.[9,10] Sadly, essential medicines (e.g., antimicrobials) are the most frequently targeted products of this type in developing

countries.[11] For example, counterfeit anthelminthics have been reported in Cambodia,[12] counterfeit antimalarials in several African countries,[13] and substandard antibiotics in India.[14] One study reported substandard amoxicillin in four Arab countries (Lebanon, Jordan, Egypt and Saudi Arabia).[15] In that study, the content of amoxicillin in capsules and suspensions was investigated, although the number of samples collected from each country and the methodology of sample collection were not specified in detail. However, the authors concluded that the prevalence of substandard amoxicillin products in these Arab countries was high.

Studies with sound and reproducible methodology on the quality of medicines in developing countries are very limited. Convenience sampling is widely used for this purpose, even though bias is clearly introduced because usually only accessible pharmacies or outlets are selected. Formal random sampling generally requires a larger sample, longer surveying time, and more resources. For these reasons, Lot Quality Assurance Sampling (LQAS) has been proposed as an economical technique to survey the quality of medicines sold in community pharmacies.[3] LQAS was developed in the 1920s to assess the quality of industrial products by inspecting random samples.[16] It was later adapted and successfully used in a variety of health care surveys and settings,[17] such as the rapid assessment of the prevalence of active trachoma,[18] assessing the prevalence of acute malnutrition,[19] evaluation of the polio eradication initiative,[20] and identifying inadequately performing areas for health services.[21] However, it was not used for surveying the quality of medicines in the supply chain. Because LQAS uses a relatively small sample, it cannot determine the prevalence (rate) of outlets that sell low-quality medicines, but rather provides a way to classify the rate as either acceptable or unacceptable in terms of predetermined criteria. Thus, it may be

helpful to enable decision makers to properly allocate and distribute resources among various supervisory areas, and also provides an indication as to whether or not larger-scale, randomized surveys are required.

In Saudi Arabia antibiotics are very commonly prescribed.[22–29] Self-medication is a common practice, and several prescription medicines, including antibiotics, can be purchased without a prescription despite the government's regulations.[22,23] Drug regulation in this country was originally the duty of the Ministry of Health (MOH), which established a strict system for pharmaceutical facilities and products. That system included detailed standards intended to ensure the best quality of medicines at all stages, from manufacturing to dispensing, if applied appropriately.[30] Recently, the Saudi Food and Drug Authority (SFDA) was established as an independent corporate body that reports directly to the President of the Council of Ministers. It is responsible for ensuring the safety of food and drugs for human and veterinary use and the safety of biological and chemical substances and medical devices. The establishment of the SFDA is still in its initial stage. By the end of this stage, all matters relating to drug regulation will be delegated to this authority.[31]

Amoxicillin is widely used because it is included in the list of essential drugs issued by the World Health Organization (WHO).[32] It is also considered an essential drug in primary health care in Saudi Arabia.[33] It is also among the most widely counterfeited medicines in developing countries.[9,11] Substandard amoxicillin has already been identified in Saudi Arabia in one study.[15] Furthermore, amoxicillin products, including suspensions and capsules, are sensitive to heat and may degrade easily at temperatures above 30 °C.[34] Therefore, amoxicillin was selected as an

indicator of the quality of medicines in the supply chain in Saudi Arabia, where high temperatures are common.

Objectives

One of the aims of this study is to field test an economical, easily reproducible and statistically valid method for monitoring the quality of medicines in community pharmacies in Riyadh, the capital of Saudi Arabia. This method estimates the proportion of pharmacies that sell poor-quality medicines relative to a predefined threshold. A finding that this threshold is exceeded is interpreted to indicate a significant problem that requires intervention by the SFDA. In addition, the results obtained with this method can help decision makers classify the quality of the provision of medicines and can therefore help with the allocation of resources. This method could be the first step in determining whether large-scale, randomized surveys are required and can serve as a baseline for future studies using the same sampling methodology. The study also provides reliable data about the quality of amoxicillin capsules and tablets sold in community pharmacies in Riyadh, as a model of an essential drug and a medicine quality indicator.

The Null Hypothesis

Based on a review of the literature on the quality of amoxicillin in developing countries[9,11,15,35,36] and considering the possible differences between these countries and Saudi Arabia (e.g., the economy and the regulatory environment), the null hypothesis was formulated that > 20% of the community pharmacies in Riyadh, either chain or independent, sell poor-quality amoxicillin.

The design of this study and the sampling technique were approved by the Ethical Committee of Kanazawa University, as well as by the SFDA. Samples were collected between September 21 and October 3, 2010, in the city of Riyadh. The samples were shipped to Kanazawa University, Japan, in temperature-preserving containers on a secure courier after obtaining the necessary clearance documents from the SFDA and the Japanese Customs Department. The analysis was performed in the Department of Drug Management and Policy at Kanazawa University between May 25, 2011 and February 7, 2012 before the expiration dates of all samples, which were kept in their original packaging under controlled room temperature of 22 °C until analysis.

Because two levels of sampling (the selection of pharmacies and the selection of amoxicillin brands) were included in this study and to avoid any confusion, the term "sample" was used to indicate amoxicillin samples and the term "subject" for the pharmacies selected for the study. The term "target pharmacy" refers to pharmacies that sell poor-quality amoxicillin.

Selection of Pharmacies

A list of registered community pharmacies and their addresses in Riyadh was obtained from the SFDA by July 2010 (1367 pharmacies). The pharmacies were then divided into two lots, chain and independent (869 and 498 pharmacies, respectively, with a total number of 82 chains). These two lots represented the sampling frames. A pharmacy was considered independent if it belonged to a group of ≤ 3 pharmacies, whereas a chain pharmacy was considered to belong to a group of ≥ 4 pharmacies.[37] These lots, rather than geographical lots, were created to assess whether the quality of

medicines in pharmacies differs according to an economy of scale and to check the possible impact of the supply chain on the quality of medicines.

The required number of pharmacies required for the investigation was calculated according to the Lot Quality Assurance Sampling (LQAS) technique. LQAS employs a binomial formula (Figure 1.1) that requires predefined upper and lower prevalence (or rate) thresholds for the target subjects in a lot to classify the lot as a high- or a low-prevalence lot in terms of the proportion of target subjects. The formula must be applied for both thresholds to calculate the probability of correctly classifying a lot at both thresholds (sensitivity and specificity) and the associated alpha and beta errors (chances or risks) of misclassification. Probability (or error) calculation is performed for all possible combinations of the numbers of subjects (target and non-target), increasing the

$$P_x = \frac{n!}{x!\,(n-x)!}\, p^x\, q^{n-x} \qquad P_x = \frac{\binom{S}{x}\binom{N-S}{n-x}}{\binom{N}{n}} \qquad a! = a\,\Gamma(a)$$

The binomial formula · The hypergeometric formula · The factorial of a fraction

P = the probability calculated at **p**.

x = decision rule (i.e., number of target pharmacies out of **n**).

n = required number of subject pharmacies.

p = the predefined prevalence (rate) threshold of target pharmacies.

q = the predefined prevalence (rate) threshold of non-target pharmacies (i.e., 1 – **p**).

S = predefined number of target pharmacies out of **N** (i.e., **p** × **N**).

N = population size of a lot.

$$\binom{a}{b} = \frac{a!}{b!\,(a-b)!}$$

$\Gamma(a) =$ the gamma function of a.

Figure 1.1. LQAS equations.

total number of subjects by 1 after each round of combinations of each total, until the minimum number of total subjects coinciding with the lowest possible combination of actual errors ($\leq$ the predefined errors) and their sum is reached at both thresholds simultaneously. At this latter combination, the total number of subjects represents the number of subjects required for the study, and the number of target subjects (associated with the condition being studied) represents the decision rule. If this decision rule is exceeded, the lot is classified as a high-prevalence lot relative to the condition under study. Otherwise, the lot is classified as a low-prevalence lot. The probabilities (or errors) obtained at each combination must be cumulative (the sum of the current and the previous values in the same round of combinations). Finally, the condition under study determines whether the lot is accepted or rejected if it is classified as either high- or low-prevalence. A consumer risk occurs when a lot is misclassified as "good" (i.e., misclassified as having a high rate of good subjects or a low rate of bad subjects), and a provider risk occurs when a lot is misclassified as "bad" (i.e., misclassified as having a high rate of bad subjects or a low rate of good subjects). The classification of an error (alpha or beta) as either a consumer risk or a provider risk depends on the formulation of the null hypothesis and, consequently, on the definitions of the thresholds.

In this study, the target subjects are the pharmacies that sell poor-quality amoxicillin. Ideally, no pharmacy in any lot would sell poor-quality medicines. However, studies from developing countries have reported a variety of rates of counterfeit and substandard antimicrobials ranging from 2.8% to more than 50%, with the majority of the rates within a range of 30–40%.[9] In addition, a variable content of amoxicillin, ranging from 0% to 85%, was reported in several studies that documented poor-quality amoxicillin.[9,11,15,35,36] Based on those studies and the specific economy

and regulatory environment in Saudi Arabia, the following upper and lower prevalence thresholds were adopted in this study: a lot with a rate of target pharmacies > 20% was classified as a high-prevalence lot (and hence rejected), whereas a lot with a rate of target pharmacies ≤ 5% was classified as a low-prevalence lot. This classification is not ideal. However, it is acceptable because it requires minimal resources relative to those needed to improve high-prevalence lots. The LQAS decision rule only classifies the rate as either > the predefined upper threshold or ≤ the predefined lower threshold. It is not sensitive to rates between these thresholds. The consumer risk (alpha error) was specified as a predetermined value of ≤ 0.05. This value represents the probability of rejecting a true null hypothesis (classifying a high-prevalence lot as low-prevalence). The provider risk (beta error) was specified as a predetermined value of ≤ 0.10. This value represents the probability of failing to reject a false null hypothesis (classifying a low-prevalence lot as high-prevalence).

The binomial LQAS formula is preferred if the population size is either unknown or very large.[38] However, the hypergeometric model of LQAS was used in this study for sample size and decision rule calculation (Figure 1.1) because each subject pharmacy was included only once and because the population size of pharmacies in each lot was known and relatively small. These characteristics allow the actual errors to be calculated more accurately.[39,40] In this model, the gamma function is used for the calculation of factorials of fractions (Figure 1.1). The minimum number of subject pharmacies that produced the lowest combination of errors at both thresholds was 36 pharmacies from each lot, with 3 as the value for the decision rule. Table 1.1 shows a part of the calculation process. If the number of pharmacies that sell poor-quality amoxicillin exceeds the decision rule, the entire lot is classified as a lot with a

high prevalence of pharmacies that sell poor-quality amoxicillin and will therefore be rejected. This outcome implies that more resources must be directed toward the lot to investigate and correct the situation. Otherwise, the lot will be classified as a low-prevalence lot, one requiring fewer resources. A calculator that uses this calculation method is available online.[41]

Table 1.1. Part of the calculation process for deciding the required number of subject pharmacies and the decision rule.

x	Sensitivity (at upper threshold = 0.20)	Cumulative alpha error (consumer risk)	Cumulative specificity (at lower threshold = 0.05)	Beta error (provider risk)	Total error
For chain pharmacies (N = 869) when n = 36					
0	0.9997	0.0003	0.1517	0.8483	0.8486
1	0.9972	0.0028	0.4519	0.5481	0.5509
2	0.9855	0.0145	0.7336	0.2664	0.2809
3	0.9512	0.0488	0.9006	0.0994	0.1482
4	0.8783	0.1217	0.9708	0.0292	0.1509
5	0.7591	0.2409	0.9931	0.0069	0.2478
6	0.6027	0.3973	0.9987	0.0013	0.3986
For independent pharmacies (N = 498) when n = 36					
0	0.9998	0.0002	0.1471	0.8529	0.8531
1	0.9975	0.0025	0.4481	0.5519	0.5544
2	0.9866	0.0134	0.7348	0.2652	0.2786
3	0.9538	0.0462	0.9039	0.0961	0.1423
4	0.8823	0.1177	0.9732	0.0268	0.1445
5	0.7633	0.2367	0.9941	0.0059	0.2426
6	0.6054	0.3946	0.9990	0.0010	0.3956

The first 7 rows of probability combinations are shown. x = decision rule, N = population size, n = required number of subject pharmacies, sensitivity = 1 – cumulative alpha error, Beta error = 1 – cumulative specificity.

Minimum accepted errors (and their sum) occur when x = 3 in the round of n when n = 36 for each lot (shaded areas of the table). This indicates that the smallest required number of subject pharmacies is 36. If the calculation continues, other good combinations will be obtained. However, this would require additional pharmacies. At n = 36, the finding of ≤ 3 target pharmacies indicates that their rate in the corresponding lot is ≤ 5%. However, this rate is acceptable according to the predefined thresholds in this study. The finding of > 3 target pharmacies means that their rate is > 20%. Because this rate is unacceptable, the corresponding lot (i.e., category of pharmacy) is rejected.

It is worth mentioning that formal random sampling would have required a 4- to 5-fold larger number of pharmacies in each category, and therefore the resources required would have been 4- to 5-fold greater. This represents a significant advantage for LQAS, especially in developing countries.

An initial alphabetical list of pharmacies in each lot was created, and each pharmacy was given a special code. Each coded list was then scrambled, and 45 (36+9) pharmacies were randomly selected from each list by one of the co-investigators with MS Excel 2010 (Microsoft Co., USA). The additional 9 pharmacies represented a reserve for an estimated dropout rate of 25%. A pharmacy could be excluded, and replaced by one from the reserve list, for any of the following reasons: (a) the pharmacy was closed on the second visit, (b) the pharmacy was out of business, (c) the pharmacy did not have a sufficient number of amoxicillin dosage units (80 units from the available brands), or (d) the pharmacy refused to sell amoxicillin without a prescription. The randomly selected pharmacies from both lots were grouped by districts to facilitate sample collection. The same district distribution used in the list of pharmacies provided by the SFDA, in which the total number of districts was 114, was followed in this study (Annex 1.1). Sampling continued until samples had been purchased from 36 pharmacies in each lot.

Amoxicillin Sampling

The "mystery shopper" technique was used in the purchasing of the samples because an unwanted change in the seller's behavior might result if the identity of the investigator was known to the seller.[42,43] Such behavioral changes might include non-cooperation or hiding poor-quality products available at the pharmacy. The investigator,

a Saudi Arabian citizen, played the role of the mystery shopper and was accompanied by two co-investigators in the field. This sampling technique was field tested prior to actual sampling and was standardized using the same scenario in each pharmacy. In this scenario, the sampler asked the seller to show him all brands of amoxicillin capsules and tablets available in 4–5 packs (80 dosage units) because one of the sampler's friends wanted the medicine. The sampler also told the seller that he would call his friend to tell him about the available brands and strengths to allow the friend to select the product to be purchased. Then, all brands and strengths that were available in sufficient quantities were numbered in a list reflecting the order in which the seller presented them, excluding any clavulanate-containing products. Each strength of a given brand was treated as a separate brand. A mobile telephone operated by Windows Mobile was used to rapidly generate a random number between 1 and the highest number on the list from Excel Mobile. This procedure was conducted while the sampler appeared to be making the call. In this way, one brand of amoxicillin capsules or tablets was randomly purchased from each randomly selected pharmacy.

If the 80 dosage units were from more than one batch, they were considered different samples purchased from the same pharmacy (i.e., a sample was a number of dosage units of the same batch purchased from a single pharmacy). Samples from the same batch of the same brand purchased from different pharmacies were considered different samples. If a sample from a pharmacy was found to be of poor quality, the pharmacy was considered a failed pharmacy.

After sampling from each pharmacy, the sampler and one of the co-investigators immediately completed the sampling form outside the pharmacy. The contents of the sampling form are shown in Table 1.2 and the sampling form is available in Annex 1.2.

Samples were immediately placed in a temperature-preserving container. The car air conditioner was operating effectively during all sampling trips. Amoxicillin brands were coded with the letters A–P.

Amoxicillin Authenticity Investigations

Dosage units, strips, boxes, and package inserts of all samples were visually inspected. Parts of all those items were sent to the corresponding manufacturers for authenticity confirmation including a special form (Annex 1.3). The SFDA was contacted to verify the registration status of the products.

Analysis and Materials

The content uniformity test was performed using high-performance liquid chromatography (HPLC) according to the 34th edition of the United States

Table 1.2. Sampling information.

Pharmacy code and type	Batch number
Sample code	Manufacture date
Sampling date	Expiration date
Package condition and type	Price
Trade name	Pharmacy name
Manufacturer's name	Pharmacy type
Manufacturer's country	Pharmacy address
Distributor in Saudi Arabia	Pharmacy general neatness
Dosage form	Exposure of shelves to sunlight
Strength	Quality of air-conditioning
Package size	Pharmacist nationality and qualification
Registration number in Saudi Arabia	Willingness of selling unregistered drugs

Pharmacopeia (USP 34).[44,45] The only difference was using a shorter HPLC column (15 cm instead of 25 cm). However, the use of the shorter column would not affect the results as long as the method was validated. All samples were submitted to the first stage of the test, which involved 10 dosage units of each sample. Failed samples were challenged at the second stage, which involved 20 additional units. However, samples that were outside the deviation range of the first stage were treated as permanently failed without the need for a second stage of testing, as indicated by the USP. For every sample the amoxicillin content, which should range from 90.0%–120.0% for capsules and 90.0%–110.0% for tablets, according to the USP, was calculated by averaging the content of the dosage units analyzed in the content uniformity test.

All chemicals used were of analytical grade. Acetonitrile, potassium dihydrogen phosphate, and potassium hydroxide were purchased from Nakalai Tesque (Kyoto, Japan). The diluent was prepared by accurately dissolving 13.6 g of potassium dihydrogen phosphate in 2000 mL of distilled water adjusted with potassium hydroxide solution to a pH of 5. The mobile phase was prepared by mixing acetonitrile and the diluent in a ratio of 4:96.

The HPLC system consisted of the following components from JASCO (Tokyo, Japan): a pump (PU–2080 Plus), a UV detector (UV–2075 Plus) set at 230 nm, a column thermostat (CO–1560), a degasser (DG–980–50), a system controller (LC–Net II/ADC), and an autosampler (AS–950). The system was equipped with a Shim–pack CLC–ODS (M) column—a 4.6×150 mm column filled with 70% methanol from Shimadzu (Kyoto, Japan). The system was linked with a computer running ChromNav software from JASCO (Tokyo, Japan) for interpreting the results and plotting curves and peaks.

Standard amoxicillin, conforming to the USP Reference Standard (USPRS), was obtained from the Department of Medical Sciences, Bureau of Drug and Narcotic, Ministry of Public Health, Thailand. Standard cefadroxil, from Sigma (St Louis, MO, USA), was used as the internal standard.

Peaks of amoxicillin and cefadroxil were observed at 6 and 8 minutes, respectively, with a flow rate of 0.6 mL/min (Figure 1.2). The linearity of the standard amoxicillin/diluent solution was maintained between 0.025 and 0.5 mg/mL and the analytical range was 0.05–0.4 mg/mL (Figure 1.3). The linearity of the standard cefadroxil/diluent solution was maintained between 0.025 and 0.2 mg/mL and the analytical range was 0.05–0.15 mg/mL (Figure 1.4).

A daily calibration curve was produced by 3 concentrations of standard amoxicillin (0.05, 0.10, and 0.2 mg/mL) prepared from a freshly prepared stock solution of 1 mg/mL (on anhydrous base). A daily stock solution of standard cefadroxil (0.2 mg/mL on anhydrous base) was freshly prepared and was added to all sample and
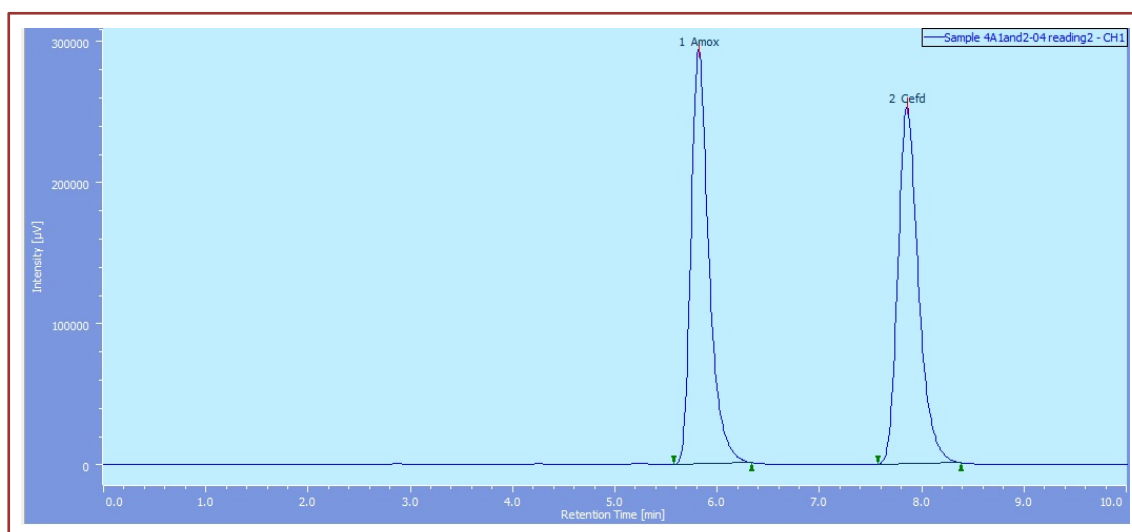
Figure 1.2. Retention times of amoxicillin and cefadroxil peaks (6 and 8 minutes, respectively). Amox = amoxicillin, and Cefd = cefadroxil.

calibration solutions to obtain a final concentration of 0.1 mg/mL in each solution (Figure 1.5).

The samples were analyzed in the order of their expiration dates. Each capsule was completely emptied, and the powder was dissolved in 200 or 400 mL of the diluent according to the capsule strength (250 or 500 mg, respectively). The flask was shaken
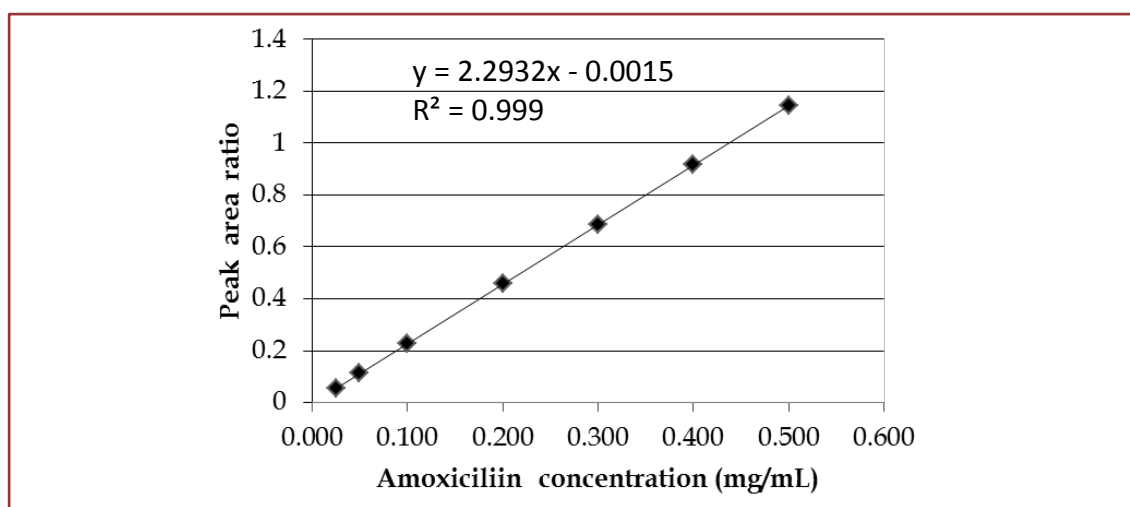
Figure 1.3. Linearity of amoxicillin solution, using cefadroxil as an internal standard.
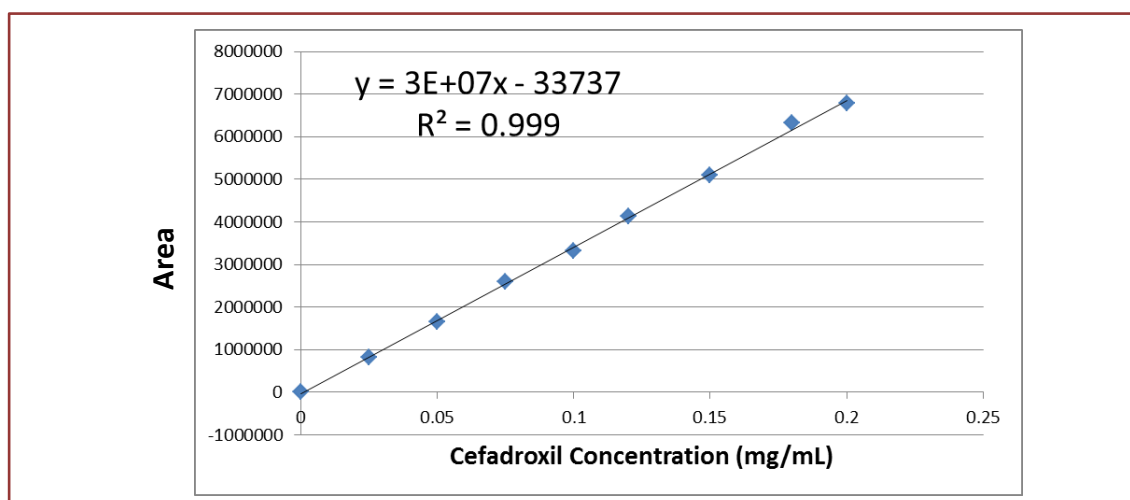
Figure 1.4. Linearity of cefadroxil solution.

vigorously 20 times and sonicated for 20 minutes. All tablets were of 500 mg strength.

Each tablet was ground to fine powder in a mortar and was then dissolved in 400 mL of

the diluent, shaken vigorously 20 times, sonicated for 5 minutes, and stirred for 30

minutes. Part of the solution was then centrifuged and the supernatant was used for

analysis. The necessary dilution was then made for each sample solution with the

diluent and the internal standard solution so that the theoretical concentration of

amoxicillin would fall within the analytical range (Figure 1.6).

The final sample and calibration solutions were filtered through 0.2 µm Minisart

RC 4 syringe filters from Sartorius Stedim (Dublin, Ireland). All solutions were used

within 6 hours of preparation and analyzed in triplicate.

For method validation, Intra- and inter-day precision were determined by

analyzing three solutions of standard amoxicillin of different concentrations (0.06, 0.12,
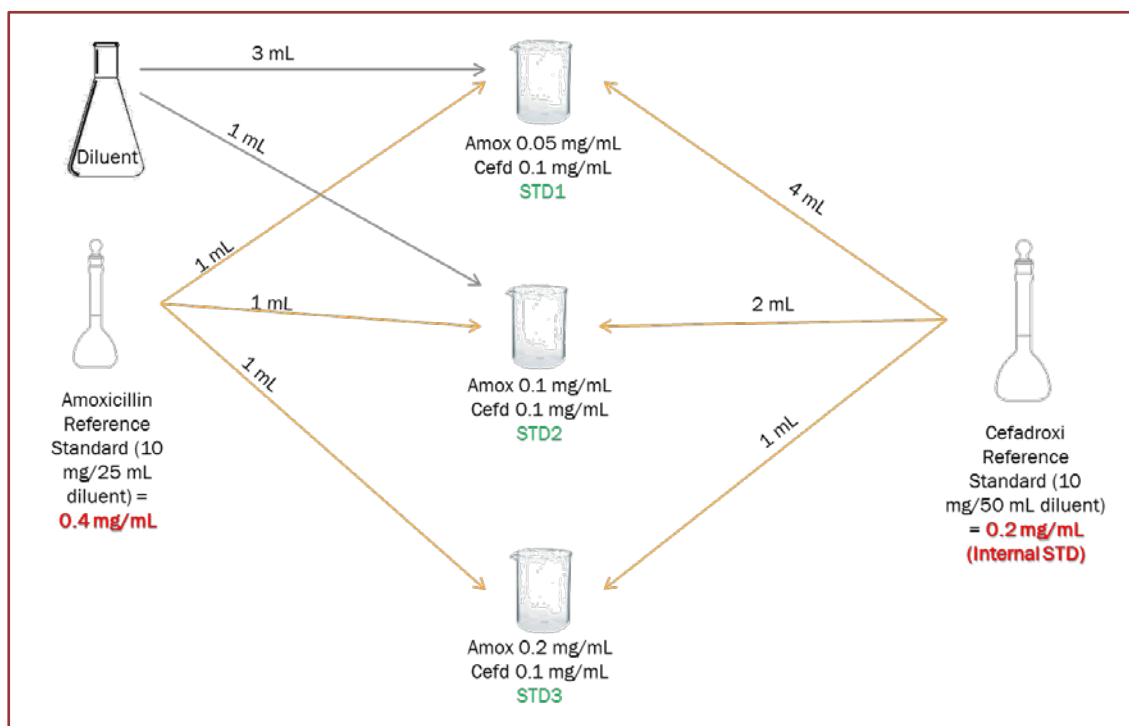
Figure 1.5. Daily preparation of amoxicillin calibration curve using cefadroxil as an internal standard. Amox = amoxicillin, Cefd = cefadroxil, STD = standard solution.

and 0.18 mg/mL) over a period of three days. An accuracy test for the method was performed by applying the standard-addition (spiking) recovery technique. Using this technique, one dosage unit from each strength of each brand of amoxicillin tablets and capsules was analyzed for amoxicillin content. Standard amoxicillin was then added to three aliquots of the pre-analyzed solution in three different concentrations (0.025, 0.05, 0.075 mg/mL), and the solutions were analyzed again to determine the total amoxicillin concentration. Finally, the recovered amount of added amoxicillin was calculated. This test was repeated three times using three dosage units, and the average recovery was calculated (Figure 1.7). All values of standard deviation, relative standard deviation, and relative error for both precision and accuracy were less than 2%, based on a 95% confidence interval. These values were considered satisfactory.
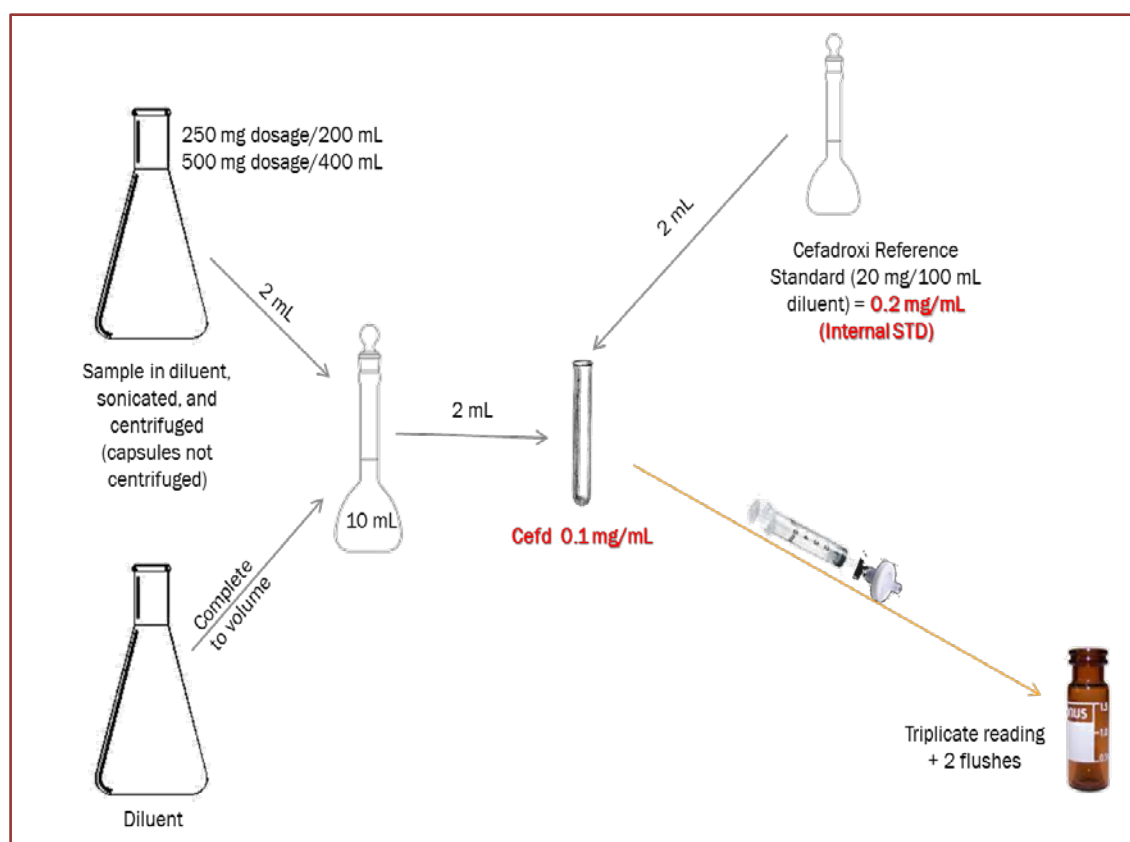
Figure 1.6. Steps for sample analysis. Cefd= cefadroxil.
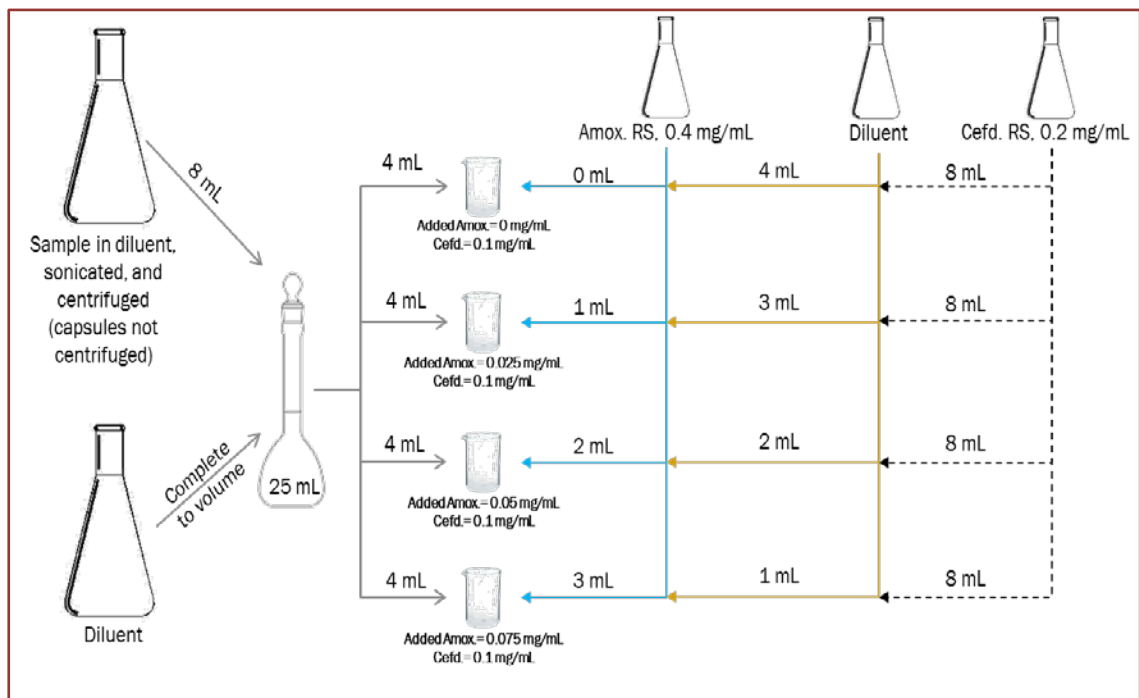
Figure 1.7. Steps for the accuracy test. Amox = amoxicillin, Cefd = cefadroxil, RS = reference standard.

Eighty-five pharmacies (43 chain and 42 independent) were visited during the sampling period in 53 of the 114 districts of Riyadh. The dropout was 7 and 6 for chain and independent pharmacies, respectively. Dropouts occurred for reasons a, b, and c, mentioned above (5, 4, and 4 pharmacies, respectively). No major differences for dropping out were found between the independent and chain lots. No pharmacies were excluded because they refused to sell amoxicillin without a prescription.

In all, 83 samples were collected from 72 randomly selected subject pharmacies. Of these samples, 41 were collected from chain pharmacies and 42 from independent pharmacies (Table 1.3 and Annex 1.4). Six samples (7%) were tablets, two of which were purchased from chain pharmacies and the rest from independent pharmacies. The remaining samples were all capsules. Twenty-eight samples (35%) were locally manufactured, 47 (57%) were imported from other Arab countries, and 7 (8%) were imported from Europe. The samples included 16 brands produced by 10 manufacturers. These samples represented all the manufacturers registered by the SFDA at the time of sampling.

Visual inspection revealed that all the samples were neatly packaged in boxes containing push-through strips and a pamphlet. All samples and packaging of each brand were identical and included the registration code in Saudi Arabia, as well as the price and the name of the distributor. The price was identical for each sample of the same brand. The batch numbers, manufacturing dates and expiration dates on the boxes and strips were found to match. Authenticity was confirmed by all manufacturers, seven of whom responded in writing and three by telephone. However, their responses to the

attached questionnaire were not complete. Finally, the registration status of each product and manufacturer was confirmed by the SFDA.

One sample was outside the deviation range of the first stage of the content uniformity test and failed the test for this reason. Fourteen samples failed the first-stage acceptance value (AV = 15%). Eight of these samples failed the second stage and hence

Table 1.3. Distribution of samples and batches.

Brand code	Number of samples[a]			Number of batches[b]
	From 36 chain pharmacies	From 36 independent pharmacies	Total	
A[c]	4	4	8	3
B[c]	4	3	7	5
C[d]	2	0	2	2
D[d]	3	4	7	6
E[d]	3	7	10	6
F[e]	1	0	1	1
G[e]	2	0	2	2
H[d]	0	1	1	1
I[d]	6	1	7	5
J[c]	1	5	6	4
K[d]	3	2	5	3
L[e]	0	4	4	3
M[d]	4	6	10	10
N[c]	2	0	2	2
O[c]	5	1	6	2
P[d]	1	4	5	3
Total	41	42	83	57

[a] A sample is a batch purchased from a single pharmacy. If the same batch is purchased at another pharmacy, it is considered as a different sample. Different batches of the same brand purchased from the same pharmacy are also considered as different samples.

[b] The number of batches of the corresponding brand purchased from all pharmacies without repetition.

[c] Manufactured in Saudi Arabia.

[d] Imported from other Arab countries.

[e] Imported from Europe.

failed the test. In all, a total of 9 samples (11%) failed the test. All of these samples were capsules. The failed samples were purchased from 9 pharmacies (4 chain and 5 independent) that belonged to different chains or owners and included five brands from four manufacturers (Figure 1.8). However, no sample for brand C was purchased from any independent pharmacy. The content of 6 of the failed samples was below 90%. The lowest content was 80.7%. The content of the approved samples ranged from 90.6% to 104.2% (Figure 1.9). Interestingly, certain batches of certain brands passed the content and/or content uniformity tests in some pharmacies, but failed in others (Table 1.4). A summary of the sample analyses can be found in Annex 1.5.

The number of pharmacies that sold poor-quality amoxicillin in each lot of pharmacies was greater than the decision value of 3. For this reason, both the chain and independent lots were rejected. As a result, the null hypothesis failed to be rejected, and both lots were classified as high-prevalence lots. This result shows that more than 20% of the pharmacies in each lot sell poor-quality amoxicillin, an outcome suggestive of a significant problem with important public health implications.

The following observations were recorded while visiting the pharmacies for sampling. The air-conditioning was totally unsatisfactory in one independent pharmacy and one medicine shelf was exposed to direct sunlight in another independent pharmacy. Neatness and cleanliness was satisfactory in all pharmacies. Surprisingly a prescription was not requested by all pharmacies, and instructions about the use of amoxicillin were not offered by all of them. It was also noted that in some pharmacies there were certain signs stating clearly that prescription-only medicines cannot be sold without prescriptions. This sign was not seen in 8 (22%) chain pharmacies and 11 (31%)

independent pharmacies. All pharmacists in the visited pharmacies were non-Saudis. Tabulated pharmacy information can be found in Annex 1.6.
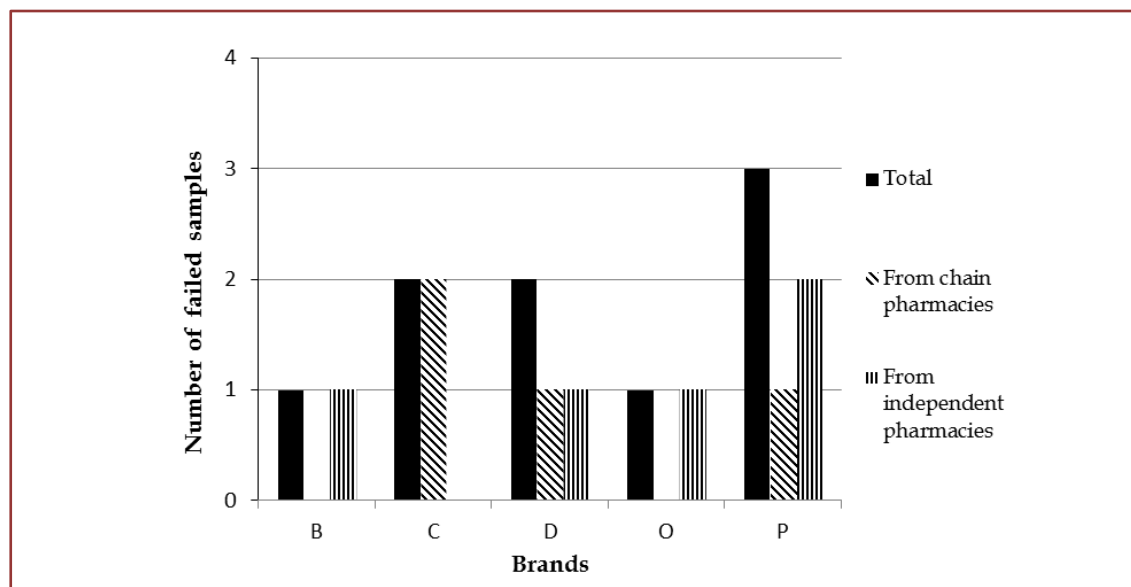
Figure 1.8. Distribution of failed samples.

Table 1.4. Batches that passed in some pharmacies but failed in others.

Brand	Samples of the same batch		Content uniformity acceptance value (%)[a]	Average content (%)	Pharmacy type
	No.	Status			
B	1	Failed	15.66	92.36	Independent
	2	Passed	07.35	94.74	Independent
D	1	Failed	19.92	86.81	Independent
	2	Passed	14.20	91.11	Independent
O	1	Failed	27.06	84.43	Independent
	2	Passed	05.57	95.96	Chain
	3	Passed	08.46	95.38	Chain
	4	Passed	13.21	93.57	Chain
P	1	Failed	15.08	90.66	Independent
	2	Failed	17.24	91.89	Independent
	3	Passed	08.26	95.41	Independent

[a] Acceptance value must be ≤ 15%.
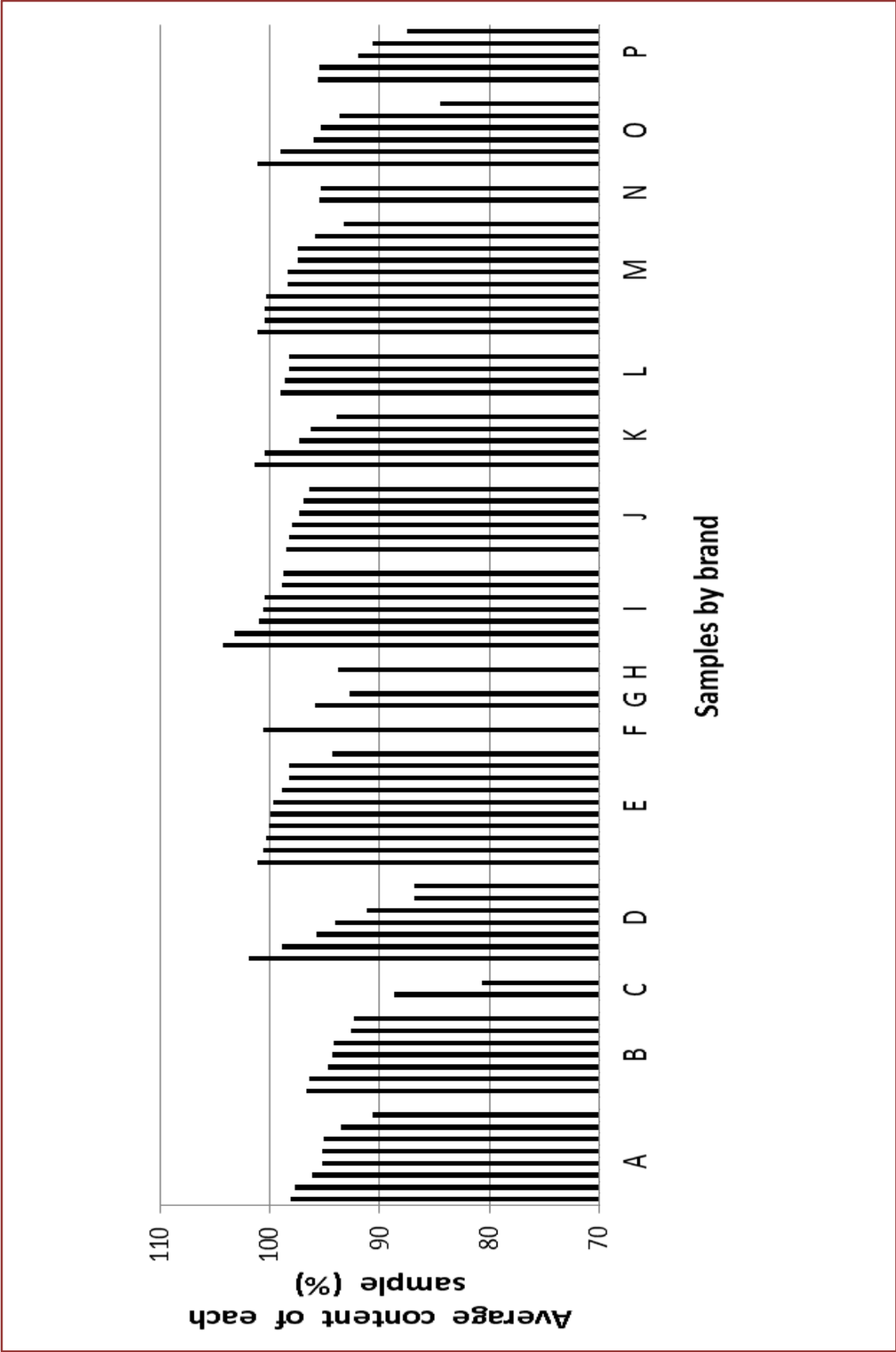
Figure 1.9. Content distribution of all samples.

Although counterfeit products were not identified by this survey, substandard samples represented 11% of the total samples. This result may indicate a high prevalence of substandard amoxicillin products in community pharmacies in Riyadh. This finding is consistent with the findings of Kyriacos et al.,[15] although the sample size for the amoxicillin products purchased in Saudi Arabia was not specified in that study. It was also found in this study, as in that previous study, that all European samples passed the quality tests used. In addition, all tablet forms passed the quality tests. However, it is difficult to perform a valid comparison due to the small percentage of European samples (8%). Similarly, it cannot be stated conclusively that tablet forms are more stable than capsules because of the small percentage of tablets (7%). However, small percentages of tablet forms and European products were expected to be found in Saudi Arabia because the sales of these items during the second quarter of 2009, expressed as percentages of the total sale of amoxicillin capsules and tablets, were 3.96% and 4.32%, respectively, according to the SFDA (personal communication).

In this study it was also found that certain batches passed the content and/or content uniformity test in certain pharmacies and failed in others. This result suggests the occurrence of degraded products that were originally of good quality and suggests that degradation may have occurred due to poor storage and/or distribution conditions (Table 1.4). In general, Riyadh climate is arid with extreme increase of temperature in summer and decrease in winter. The samples were collected during a very hot season, when the outside temperature in Riyadh during the daytime reached approximately 45 °C. Poor temperature control in the distributors' facilities, such as warehouses and delivery vehicles, could have been resulted in the degradation of amoxicillin. Also,

although the air conditioning in the vast majority of the visited pharmacies was satisfactory during sampling, the possibility that the air conditioners failed or were not used in certain pharmacies at certain times cannot be excluded. In addition, possible poor quality control practices during the manufacturing of several other batches that totally failed cannot be excluded. This hypothesis is supported by the appearance of the powder of the capsules of several failed samples from a certain manufacturer. The powder was in the form of a hard mass that appeared to have formed when the sample became dry after having been in a hygroscopic state. This observation suggests that the problem was caused by poor packaging.

The average content of the active ingredient in the failed samples was greater than 80%. This value contrasts with the low values found by Kyriacos et al. (59%).[15] A lower content of amoxicillin was also reported in another study in Nigeria. Only 24% of the amount shown on the label was found in that study.[35] Counterfeit or substandard amoxicillin was found in several countries. The reported amoxicillin content of these products varied, reaching zero in certain cases.[9] However, the results of this study seem consistent with the findings of a study conducted in Indonesia, where 20% of the amoxicillin tablets analyzed contained an amount of active ingredient slightly below the lower acceptable range according to the British Pharmacopeia (BP).[36] It should be noted that in this study, based on the content range of 92.5–110% specified in the BP 2012,[46] two more samples would have failed the content test (one sample from each lot).

Nevertheless, the existence of a substandard essential medicine in community pharmacies in Riyadh, a capital city where inspection and monitoring are expected to be relatively strict, suggests that poor-quality medicines with a lower content of the active

ingredient would be prevalent in other cities or in remote areas of the country due to less strict monitoring and control and less satisfactory storage and/or distribution conditions.

In addition, the problem appears to exist regardless of the economy of scale of pharmacies (chain or independent). The number of pharmacies selling poor-quality amoxicillin exceeded the decision value in both lots. For this reason, the lots were both considered to have high prevalence rates. This finding suggests that possible intervention strategies should target both types of community pharmacies, regardless of the anticipated quality of the service provided.

The LQAS technique with a mystery shopper provided a readily reproducible and statistically valid sample collection method that requires a small sample. The use of this method is recommend for future monitoring by the SFDA or other investigators in Saudi Arabia. It is also recommended that that this methodology be followed as a model for investigating the quality of other medicines and pharmacies in Saudi Arabia, and probably other countries. This methodology can be also used as a follow-up technique to monitor the changes that may occur following suitable intervention. However, the medicine selected as an indicator of the quality of medicines may need to be changed according to the geographical area surveyed. In this study, amoxicillin was selected because it is widely used, widely counterfeited, and heat-labile (Riyadh is very hot during summer), and also because substandard amoxicillin was reported in Saudi Arabia in one study.

In theory, LQAS sampling can be terminated if the decision rule is exceeded at an early stage of the survey. In this way, the target can be achieved with minimal cost and time. The termination of sampling at an early stage was not possible in this study, but this outcome may be achieved for other analytical procedures that can be conducted

in the field. In addition, the results of the survey could indicate whether large-scale, randomized surveys are required for further investigation of the problem.

Limitations

The following limitations may have affected the extent to which the results of this study can be generalized. First, only capsule and tablet dosage forms were sampled because suspension bottles are bulky and may break easily during shipping to Japan, where the analysis was performed. Therefore, the findings of this study cannot be expanded to other amoxicillin dosage forms.

Second, it was not possible to collect samples of a single batch from each pharmacy because asking the seller about batches would have revealed that the pharmacy was under investigation. As a result, more than one sample was obtained from several pharmacies. However, if a sample from a given pharmacy failed in the analysis, then the pharmacy failed in the lot, regardless of the quality of the other sample(s) purchased from the same pharmacy.

Third, samples were analyzed in the order of their expiration dates by the investigator, who was not blinded as to the samples being analyzed, but was blinded as to the pharmacies from which the sample(s) were obtained. Unintentional expectation bias might have been introduced because the investigator is a Saudi Arabian clinical pharmacist. However, this factor is unlikely to have affected the results of the study because several samples failed from certain pharmacies but passed from others and because the samples were repeatedly measured with a validated method.

Fourth, only content and content uniformity tests were applied in this study. The analysis of impurities or excipients was not performed, nor the dissolution test.

Therefore, "quality" in this study refers only to the acceptable amount and uniformity of the active ingredient in terms of the range specified by the USP. If the amount of active ingredient was outside the range, it was concluded that the sample failed, irrespective of other quality parameters. Moreover, degradation products were not analyzed for characterizing the failed samples as substandard or degraded. However, some samples passed the tests while other samples from the same batch but purchased from different pharmacies failed them, a finding suggestive of the degradation issues. There are several methods that can differentiate between degraded and originally substandard amoxicillin.[47,48] These methods may be used in future studies.

Finally, because LQAS requires smaller sample sizes, this study does not provide an accurate estimate of the prevalence of poor-quality amoxicillin or of poor-quality pharmacies. However, the objective was not to provide an accurate prevalence rate but to classify reliably whether the prevalence rate of poor-quality medicines or pharmacies was above or below the threshold defined in the null hypothesis. With a larger sample size, which requires more resources for sampling and analysis, stratified random sampling is still the best method for accurate prevalence estimation. However, the LQAS method could help decision makers with limited resources to classify health system services, such as the provision of medicines in community pharmacies, according to a predetermined threshold. The results of such analyses could help decision makers allocate the resources intended for improvement accordingly even if the number of rejected pharmacies in any lot is less than the decision rule.

Although this study has several limitations, it can be concluded from its results that deficiencies in the quality control of the supply chain and/or storage exist in Riyadh, either at the level of wholesalers or pharmacies, in addition to possible manufacturing defects for certain brands of amoxicillin. Based on this conclusion, the SFDA is advised to perform routine monitoring of wholesalers and pharmacy storage facilities, distribution facilities, and environmental settings inside pharmacies (e.g., temperature, humidity and exposure to sunlight). In addition, distributors, pharmacy owners, and pharmacists should be educated about the possible consequences of failing to adhere to appropriate distribution and storage conditions for the provision of medicines.

Quality inspection at the level of manufacturing must also be strengthened, and optimal conditions must be maintained during the clearance of imported medicines.

Finally, it is strongly recommend that additional research similar to the current study be conducted to investigate the quality of provision for other medicines in Riyadh and other areas of Saudi Arabia, as well as the quality of community pharmacies in terms of their adherence to the optimal conditions for keeping and selling medicines and the services provided by these pharmacies. Larger-scale randomized surveys would be helpful to further delineate the scale of the quality-control problem in Saudi Arabia.

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Annex 1.1. Maps

Map of Saudi Arabia. Riyadh is represented by a red dot.

Map of Riyadh showing its districts. Surveyed districts are marked with red dots.

Annex 1.2. Sampling form

Sampling Form
Quality of Amoxicillin Capsules and Tablets
at Private Pharmacies in Riyadh, Saudi
Arabia: LQAS Survey

Pharmacy Code: SAR-10-PH - C/I - ☐☐☐
Sample Code: SAR-10-AM - C/T - ☐☐☐
Date Purchased: D D / M M / 2010

Product Information

Package Condition	○ 1. Loose	○ 3. PTP/SP	○ 5. Packaged PTP/SP	○ Pamphlet Absent
	○ 2. Broken Seal	○ 4. Sealed	○ _____	○ Pamphlet Present

Trade Name	○ Amoxil®	○ Glomox®	○ Ospamox®	○ *Unknown*
	○ Amoxydar®	○ Hymox®	○ Penamox®	○ _____
	○ E Mox®	○ Julphamox®	○ Remox®	○ Different from Package
	○ Flemoxin®	○ Omacillin®	○ Ultramox®	○ Identical to Package

Manufacturer's Name	○ SPIMACO	○ Dar Al-Dawa	○ EPICO	○ _____
	○ Al-Hikma	○ Global Pharma	○ JULPHAR	
	○ Astellas Pharma Europe B. V.	○ APM	○ Sandoz GMBH	○ Different from Package
	○ Oman National Co. for Pharmaceutical Industries	○ Jazeera Pharmaceutical Industries	○ *Unknown*	○ Identical to Package

Manufacturer's Country	○ Saudi Arabia	○ Jordan	○ Bulgaria
	○ United Arab Emirates	○ Egypt	○ *Unknown*
	○ Oman	○ Austria	○ _____

Product Information *(cont.)*

Distributor in Saudi Arabia	○ Al-Salihiyya	○ Ibrahim Al-Manea	○ Khalid Bin Saad
	○ Farouq and Mamoun Tamr	○ Siqala	○ *Unknown*
	○ Al-Qusaibi	○ Al-Muttahida	○ _____

Dosage Form	○ Capsules ○ Tablets:	☐ Regular	☐ Dispersible	☐ Effervescent	☐

Strength	○ 250 mg	○ 500 mg	☐ Other/Comments:

Package Size	○ 20 Capsules/Tablets	○ 16 Capsules/Tablets	☐ Other/Comments:

Registration No.	○ _____	○ *Missing*	☐ Other/Comments:

Batch/Lot No.	On Package	○ _____	○ *Missing*	○ Different	☐ Other/Comments:
	On PTP/SP	○ _____	○ *Missing*	○ Identical	

Manufacture Date	On Package	○ _____	○ *Missing*	○ Different	☐ Other/Comments:
	On PTP/SP	○ _____	○ *Missing*	○ Identical	

Expiry Date	On Package	○ _____	○ *Missing*	○ Different	☐ Other/Comments:
	On PTP/SP	○ _____	○ *Missing*	○ Identical	

Price	☐ Per Capsule/Tablet:	☐ Per PTP/SP:	☐ Per Package:

Qnt'y Purchased	☐ Per Capsule/Tablet:	☐ Per PTP/SP:	☐ Per Package:

Outlet Information

Name	

Type	○ Chain-Pharmacy	○ Independent Pharmacy	○ Wholesaler	○ Illegal Outlet
	☐ Other/Comments:			

Location/ Address	☐ District:	☐ Street:
	☐ Other (Tel. / Email / P.O. Box, etc):	

Neatness	○ Excellent	○ Good	○ Poor	☐ Other/Comments:

Sunlight	○ Away from medicines	○ Close to medicines

Air-Conditioning	○ Excellent	○ Good	○ Poor	☐ Other/Comments:

Staff Information	☐ Nationality:	☐ Qualification:	☐ Willingness to sell unregistered Medicines (yes/no):

Summary

Overall Visual Check of the Product	

Comments		Signature

Annex 1.3. Manufacturer authenticity check form

KANAZAWA UNIVERSITY

Institute of Medical, Pharmaceutical
and Health Sciences

-----------Date------------

To : The Manager/Director/Other:…………
Company
Address

From : **Hani M. Khojah**
Pharmacist, Ph.D. candidate
Department of Drug Management and Policy,
Kanazawa University, Japan

RE : **Confirmation of authenticity of a medicine**

Dear Sir/Madam

As you definitely know, the market of counterfeit medicines is growing worldwide with all the possible hazards to consumers, providers, and national health systems.

I am conducting a research on the quality of medicines in the Kingdom of Saudi Arabia (KSA) under the approval of the Saudi Food and Drug Authority (SFDA). I have already collected medicine samples from a variety of private pharmacies in Riyadh, KSA. Some of the samples belong to your company, as stated on the packages.

Find please attached the following items (see the table below for details):
- … plastic bags, each containing one sample:
  - ✓ Each bag has a label on it.
  - ✓ On the label, the bag number and the sample code number are written.
  - ✓ The bag number is written on the label inside a circle and in red color.
  - ✓ Some samples may contain only a small part of the medicine strip (2 capsules/ tablets), with or without the medicine box and pamphlet (package insert). This is intentional because I do not have enough number of boxes and/or dosage forms of certain samples. You can find scanned images or photos of the boxes, pamphlets, and full strips of such samples in the attached compact disc (CD) (see below).

- A CD that contains the following:
  - ✓ Photos and scanned images of the boxes, pamphlets, and full strips of all samples including those samples that were sent as only a small part of the medicine strip (mentioned above).
  - ✓ Folder names in the CD are similar to sample code numbers.
  - ✓ A copy of this letter and the attached forms (in Microsoft Word 2007 Document format) that may make it easier for you to fill in.

Bag No.	Code Number on the bag and in the CD	Medicine Name, Strength, and Dosage Form	Contents of the Bag			
			Medicine Box	Pamphlet	1 Full Strip	2 Dosage Forms in a Cut Strip
1						
2						
3						
4						

Kindly contribute to this research by confirming the authenticity of the attached samples (Form 1) and filling out the attached questionnaire (Form 2), and reply to me at your earliest convenience (preferably before January 15, 2011) either by post, fax, or email.

Your contribution is valuable and I assure you that all the information will be confidential and for the scientific research. The names of your products will not be declared in the publication but, upon your agreement, I can mention the name of your company in the acknowledgement section. I also can send you the results of my analysis upon your request.

Thanking you in anticipation for your valuable response and cooperation.

With my best regards,

Hani M. Khojah

For: Kazuko Kimura, Professor, PhD
Department of Drug Management and Policy,
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KANAZAWA UNIVERSITY

Institute of Medical, Pharmaceutical
and Health Sciences

Authenticity Report
(Form 1)

\<Company Name\>

Kindly fill in and sign this report after examining the attached samples, indicating whether each sample is authentic or counterfeit (fill the corresponding circle in the table below).

If you find out that some samples are counterfeit, please inform me about the visual characteristics that distinguish the authentic product from the counterfeit (in the "Comments" column).

It will be more appreciated if you attach a detailed report of the authenticity check and if you reply on your company's letterhead paper.

Bag No.	Code Number on the bag and in the CD	Medicine Name, Strength, and Dosage Form	Batch Number	Manufac-turing Date	Expiry Date	Authenticity Check		Comments
						Authentic	Counterfeit	
1						○	○	
2						○	○	
3						○	○	
4						○	○	

Name : ....

Signature : ....

Job Title : ....

Tel. : ....

Fax. : ....

E-mail : ....

Company Name : ....

Company Address : ....

Company Tel. : ....

Company Fax. : ....

Company E-mail : ....

Questionnaire
(Form 2)

<Company Name>

Kindly fill in and sign this questionnaire. It will be more appreciated if you reply on your company's letterhead paper.

Q1	Is your company certified as applying good manufacturing practice (GMP)?
	○ Yes ○ No Certifying authority: ....

Q2	How often does your company survey the market for the quality of its products (post-marketing)?
	○ Annually ○ Semiannually ○ Quarterly ○ Monthly ○ Other: ....

Q3	Have your company ever encountered a counterfeit product bearing its name?
	○ Yes ○ No

Q4	If the answer to question 3 is "Yes" then in which country/countries did your company encounter the counterfeit product?
	....

Q5	Have your company ever encountered a substandard or degraded product of its own in the market (eg, due to poor storage by wholesalers or pharmacies)?
	○ Yes ○ No

Q6	If the answer to question 5 is "Yes" then in which country/countries did your company encounter the substandard or degraded product?
	....

Q7	If your company encounter a counterfeit product bearing its name, will it contact the authorities in the country where it is found?
	○ Yes ○ No ○ Other: ....

Q8	Assuming that the attached product samples are authentic, which pharmacopeia does your company refer to for quality control tests of this product before marketing?
	○ United States ○ British ○ European ○ Japanese ○ Other: ....

Q9	Please list the quality control tests and analyses used by your company for this product before marketing including description, characteristics, identification, appearance, dosage weight variation, uniformity of dosage units, dissolution, disintegration, active pharmaceutical ingredient content/potency, and stability. You can add fields to the table below or increase the size, if necessary.

Test/Analysis	Acceptance Criteria

Q10	Would you like me to send the results of my analysis to your company? ○ Yes ○ No
Q11	Would your company like me to mention its name in the acknowledgement section of the publication? *If yes, then please provide me with an official consent issued by your company.* ○ Yes ○ No

Name   : ....

Signature : ....

Job Title : ....

Tel.   : ....

Fax.   : ....

E-mail   : ....

Company Name : ....

Company Address : ....

Company Tel. : ....

Company Fax. : ....

Company E-mail : ....

Annex 1.4. Samples information

No.	Pharmacy Type (I = Independent, C = Chain)	Pharmacy Code	Sample Code	Date of Purchase	Batch No.	No. of Purchased Packages	No. of Dosage Units/ Package	Brand Code	Strength (mg)	Dosage Form	Manufacturer Code	Manufacturing Country	Expiry Date
1	I	SAR-10-PH-I-1179	SAR-10-AM-C-001	21/09/2010	34405	4	20	A	250	Capsules	M1	Saudi Arabia	2014/01
2	I	SAR-10-PH-I-0708	SAR-10-AM-C-002	21/09/2010	39193	4	20	J	500	Capsules	M1	Saudi Arabia	2012/10
3	C	SAR-10-PH-C-0160	SAR-10-AM-C-003	21/09/2010	3421	2	20	N	250	Capsules	M9	Saudi Arabia	2011/10
4	C	SAR-10-PH-C-0160	SAR-10-AM-C-003	21/09/2010	3428	2	20	N	250	Capsules	M9	Saudi Arabia	2011/10
5	I	SAR-10-PH-I-0338	SAR-10-AM-C-004	21/09/2010	1002223	5	16	E	500	Capsules	M3	Egypt	2013/03
6	C	SAR-10-PH-C-1103	SAR-10-AM-C-005	21/09/2010	2135	4	20	M	500	Capsules	M8	Jordan	2012/05
7	C	SAR-10-PH-C-1113	SAR-10-AM-C-006	21/09/2010	925	4	20	K	500	Capsules	M6	United Arab Emirates	2014/02
8	I	SAR-10-PH-I-0755	SAR-10-AM-C-007	21/09/2010	38949	4	20	J	500	Capsules	M1	Saudi Arabia	2012/10
9	C	SAR-10-PH-C-1069	SAR-10-AM-C-008	21/09/2010	617E	3	20	C	250	Capsules	M2	Jordan	2013/09
10	I	SAR-10-PH-I-1018	SAR-10-AM-C-009	22/09/2010	613E	4	20	D	500	Capsules	M2	Jordan	2013/09
11	I	SAR-10-PH-I-1244	SAR-10-AM-C-010	22/09/2010	38949	4	20	J	500	Capsules	M1	Saudi Arabia	2012/10
12	C	SAR-10-PH-C-0586	SAR-10-AM-C-011	22/09/2010	6783	1	20	I	500	Capsules	M5	United Arab Emirates	2012/10
13	C	SAR-10-PH-C-0586	SAR-10-AM-C-012	22/09/2010	6782	2	20	I	500	Capsules	M5	United Arab Emirates	2012/10
14	I	SAR-10-PH-I-0863	SAR-10-AM-C-012	22/09/2010	34731	4	20	B	500	Capsules	M1	Saudi Arabia	2014/02
15	I	SAR-10-PH-I-0329	SAR-10-AM-C-013	22/09/2010	34730	4	20	B	500	Capsules	M1	Saudi Arabia	2014/02
16	C	SAR-10-PH-C-0412	SAR-10-AM-C-014	22/09/2010	34732	3	20	B	500	Capsules	M1	Saudi Arabia	2014/02
17	C	SAR-10-PH-C-0040	SAR-10-AM-C-015	22/09/2010	33207	4	20	J	500	Capsules	M1	Saudi Arabia	2011/10
18	I	SAR-10-PH-I-0949	SAR-10-AM-C-016	22/09/2010	1618	3	20	M	500	Capsules	M8	Jordan	2011/04
19	I	SAR-10-PH-I-0949	SAR-10-AM-C-017	22/09/2010	1617	1	20	M	500	Capsules	M8	Jordan	2011/04
20	C	SAR-10-PH-C-0247	SAR-10-AM-C-017	22/09/2010	954034	4	20	P	500	Capsules	M10	Jordan	2012/05
21	C	SAR-10-PH-C-0121	SAR-10-AM-C-018	22/09/2010	3911	2	20	O	500	Capsules	M9	Saudi Arabia	2012/06
22	C	SAR-10-PH-C-0121	SAR-10-AM-C-019	23/09/2010	6004	2	20	O	500	Capsules	M9	Saudi Arabia	2013/01
23	C	SAR-10-PH-C-0877	SAR-10-AM-C-020	23/09/2010	614E	4	20	D	500	Capsules	M2	Jordan	2013/09
24	C	SAR-10-PH-C-0898	SAR-10-AM-C-021	23/09/2010	954025	4	20	P	500	Capsules	M10	Jordan	2012/04
25	I	SAR-10-PH-I-0358	SAR-10-AM-C-022	23/09/2010	40791	4	20	J	500	Capsules	M1	Saudi Arabia	2012/12
26	I	SAR-10-PH-I-1285	SAR-10-AM-C-023	23/09/2010	39193	4	20	J	500	Capsules	M1	Saudi Arabia	2012/10
27	I	SAR-10-PH-I-0893	SAR-10-AM-C-024	23/09/2010	6782	4	20	I	500	Capsules	M5	United Arab Emirates	2012/10
28	C	SAR-10-PH-C-0998	SAR-10-AM-C-025	24/09/2010	35362	4	20	B	500	Capsules	M1	Saudi Arabia	2014/03
29	C	SAR-10-PH-C-0499	SAR-10-AM-C-026	24/09/2010	6869	4	20	I	500	Capsules	M5	United Arab Emirates	2013/02
30	I	SAR-10-PH-I-0704	SAR-10-AM-C-027	25/09/2010	2394	3	20	M	500	Capsules	M8	Jordan	2012/11
31	I	SAR-10-PH-I-0704	SAR-10-AM-C-027	25/09/2010	1570	1	20	M	500	Capsules	M8	Jordan	2011/04
32	C	SAR-10-PH-C-0100	SAR-10-AM-C-028	25/09/2010	34731	2	20	B	500	Capsules	M1	Saudi Arabia	2014/02
33	C	SAR-10-PH-C-0100	SAR-10-AM-C-029	25/09/2010	34729	2	20	B	500	Capsules	M1	Saudi Arabia	2014/02
34	I	SAR-10-PH-I-0124	SAR-10-AM-C-030	25/09/2010	043F	4	20	D	500	Capsules	M2	Jordan	2013/12
35	C	SAR-10-PH-C-0791	SAR-10-AM-C-031	27/09/2010	1002225	4	16	E	500	Capsules	M3	Egypt	2013/09
36	C	SAR-10-PH-C-0788	SAR-10-AM-C-032	27/09/2010	3911	4	20	O	500	Capsules	M9	Saudi Arabia	2012/06
37	I	SAR-10-PH-I-0236	SAR-10-AM-C-033	27/09/2010	1002224	4	16	E	500	Capsules	M3	Egypt	2013/03
38	I	SAR-10-PH-I-0839	SAR-10-AM-C-034	27/09/2010	877	3	20	K	500	Capsules	M6	United Arab Emirates	2012/10
39	I	SAR-10-PH-I-0335	SAR-10-AM-C-035	27/09/2010	6316	4	20	H	250	Capsules	M5	United Arab Emirates	2011/05
40	C	SAR-10-PH-C-0332	SAR-10-AM-C-036	27/09/2010	1687	4	20	M	500	Capsules	M8	Jordan	2011/06
41	C	SAR-10-PH-C-0914	SAR-10-AM-C-037	28/09/2010	609E	4	20	D	500	Capsules	M2	Jordan	2013/09

No.	Pharmacy Type (I = Independent, C = Chain)	Pharmacy Code	Sample Code	Date of Purchase	Batch No.	No. of Purchased Packages	No. of Dosage Units/Package	Brand Code	Strength (mg)	Dosage Form	Manufacturer Code	Manufacturing Country	Expiry Date
42	I	SAR-10-PH-I-1080	SAR-10-AM-C-038	28/09/2010	1002223	5	16	E	500	Capsules	M3	Egypt	2013/03
43	I	SAR-10-PH-I-0099	SAR-10-AM-C-039	28/09/2010	31782	4	20	A	250	Capsules	M1	Saudi Arabia	2013/10
44	I	SAR-10-PH-I-0930	SAR-10-AM-C-040	28/09/2010	2128	3	20	M	500	Capsules	M8	Jordan	2012/05
45	I	SAR-10-PH-I-0930	SAR-10-AM-C-040	28/09/2010	2273	1	20	M	500	Capsules	M8	Jordan	2012/08
46	C	SAR-10-PH-C-0258	SAR-10-AM-C-041	28/09/2010	34405	4	20	A	250	Capsules	M1	Saudi Arabia	2014/01
47	C	SAR-10-PH-C-1166	SAR-10-AM-C-042	28/09/2010	044F	4	20	D	500	Capsules	M2	Jordan	2013/12
48	I	SAR-10-PH-I-0816	SAR-10-AM-C-043	28/09/2010	896	4	20	K	500	Capsules	M6	United Arab Emirates	2013/07
49	C	SAR-10-PH-C-1312	SAR-10-AM-C-044	28/09/2010	6940	4	20	I	500	Capsules	M5	United Arab Emirates	2014/04
50	C	SAR-10-PH-C-0422	SAR-10-AM-C-045	30/09/2010	617E	4	20	C	250	Capsules	M2	Jordan	2013/09
51	C	SAR-10-PH-C-0655	SAR-10-AM-C-047	30/09/2010	1002220	1	16	E	500	Capsules	M3	Egypt	2013/03
52	C	SAR-10-PH-C-0655	SAR-10-AM-C-047	30/09/2010	1002224	4	16	E	500	Capsules	M3	Egypt	2013/03
53	I	SAR-10-PH-I-0270	SAR-10-AM-C-048	30/09/2010	1000922	5	16	E	500	Capsules	M3	Egypt	2013/01
54	C	SAR-10-PH-C-0401	SAR-10-AM-C-049	30/09/2010	08G01/97	4	20	F	500	Capsules	M4	The Netherlands	2011/07
55	I	SAR-10-PH-I-0615	SAR-10-AM-C-050	30/09/2010	1002223	5	16	E	500	Capsules	M3	Egypt	2013/03
56	C	SAR-10-PH-C-1289	SAR-10-AM-C-051	30/09/2010	6004	4	20	O	500	Capsules	M9	Saudi Arabia	2013/01
57	I	SAR-10-PH-I-0213	SAR-10-AM-C-052	30/09/2010	6004	4	20	O	500	Capsules	M9	Saudi Arabia	2013/01
58	I	SAR-10-PH-I-0026	SAR-10-AM-C-053	30/09/2010	34730	3	20	B	500	Capsules	M1	Saudi Arabia	2014/02
59	C	SAR-10-PH-C-0104	SAR-10-AM-C-054	30/09/2010	6772	4	20	I	500	Capsules	M5	United Arab Emirates	2012/10
60	C	SAR-10-PH-C-1232	SAR-10-AM-C-055	30/09/2010	31782	3	20	A	250	Capsules	M1	Saudi Arabia	2013/10
61	C	SAR-10-PH-C-0502	SAR-10-AM-C-056	01/10/2010	925	4	20	K	500	Capsules	M6	United Arab Emirates	2014/02
62	I	SAR-10-PH-I-0645	SAR-10-AM-C-057	01/10/2010	31782	2	20	A	250	Capsules	M1	Saudi Arabia	2013/10
63	I	SAR-10-PH-I-0645	SAR-10-AM-C-057	01/10/2010	31277	2	20	A	250	Capsules	M1	Saudi Arabia	2013/10
64	I	SAR-10-PH-I-0079	SAR-10-AM-C-058	01/10/2010	954034	4	20	P	500	Capsules	M10	Jordan	2012/05
65	I	SAR-10-PH-I-0676	SAR-10-AM-C-059	01/10/2010	1002226	5	16	E	500	Capsules	M3	Egypt	2013/03
66	C	SAR-10-PH-C-0459	SAR-10-AM-C-060	01/10/2010	045F	4	20	D	500	Capsules	M2	Jordan	2013/12
67	C	SAR-10-PH-C-0993	SAR-10-AM-C-061	01/10/2010	2362	4	20	M	500	Capsules	M8	Jordan	2012/11
68	C	SAR-10-PH-C-0718	SAR-10-AM-C-062	01/10/2010	896	4	20	K	500	Capsules	M6	United Arab Emirates	2013/07
69	I	SAR-10-PH-I-1001	SAR-10-AM-C-063	01/10/2010	1000922	5	16	E	500	Capsules	M3	Egypt	2013/01
70	C	SAR-10-PH-C-1303	SAR-10-AM-C-064	01/10/2010	6004	4	20	O	500	Capsules	M9	Saudi Arabia	2013/01
71	I	SAR-10-PH-I-0230	SAR-10-AM-C-066	02/10/2010	613E	4	20	D	500	Capsules	M2	Jordan	2013/09
72	I	SAR-10-PH-I-1025	SAR-10-AM-C-067	02/10/2010	954034	4	20	P	500	Capsules	M10	Jordan	2012/05
73	C	SAR-10-PH-C-0074	SAR-10-AM-C-068	02/10/2010	2006	4	20	M	500	Capsules	M8	Jordan	2012/03
74	C	SAR-10-PH-C-1060	SAR-10-AM-C-069	02/10/2010	6782	4	20	I	500	Capsules	M5	United Arab Emirates	2012/10
75	C	SAR-10-PH-C-0696	SAR-10-AM-C-070	02/10/2010	31782	4	20	A	250	Capsules	M1	Saudi Arabia	2013/10
76	C	SAR-10-PH-C-1295	SAR-10-AM-C-072	02/10/2010	31277	4	20	A	250	Capsules	M1	Saudi Arabia	2013/10
77	I	SAR-10-PH-I-0959	SAR-10-AM-C-074	02/10/2010	954042	4	20	P	500	Capsules	M10	Jordan	2012/06
78	I	SAR-10-PH-I-0939	SAR-10-AM-T-009	22/09/2010	A19306	1	20	L	500	Tablets	M7	Austria	2012/03
79	I	SAR-10-PH-I-0939	SAR-10-AM-T-009	22/09/2010	A19307	3	20	L	500	Tablets	M7	Austria	2012/03
80	I	SAR-10-PH-I-0828	SAR-10-AM-T-036	27/09/2010	A19306	1	20	L	500	Tablets	M7	Austria	2012/03
81	I	SAR-10-PH-I-0828	SAR-10-AM-T-036	27/09/2010	158390	3	20	L	500	Tablets	M7	Austria	2011/08
82	C	SAR-10-PH-C-0406	SAR-10-AM-T-046	30/09/2010	09G19/56	4	20	G	500	Tablets	M4	The Netherlands	2012/07
83	C	SAR-10-PH-C-0239	SAR-10-AM-T-071	02/10/2010	08E29/56	4	20	G	500	Tablets	M4	The Netherlands	2011/05

Annex 1.5. Summary of the sample analysis results

No.	Sample Code	Unit 1 Content (% of Label Claim)	Unit 2 Content (% of Label Claim)	Unit 3 Content (% of Label Claim)	Unit 4 Content (% of Label Claim)	Unit 5 Content (% of Label Claim)	Unit 6 Content (% of Label Claim)	Unit 7 Content (% of Label Claim)	Unit 8 Content (% of Label Claim)	Unit 9 Content (% of Label Claim)	Unit 10 Content (% of Label Claim)	Unit 11 Content (% of Label Claim)	Unit 12 Content (% of Label Claim)	Unit 13 Content (% of Label Claim)	Unit 14 Content (% of Label Claim)	Unit 15 Content (% of Label Claim)	Unit 16 Content (% of Label Claim)	Unit 17 Content (% of Label Claim)	Unit 18 Content (% of Label Claim)	Unit 19 Content (% of Label Claim)	Unit 20 Content (% of Label Claim)	Unit 21 Content (% of Label Claim)	Unit 22 Content (% of Label Claim)	Unit 23 Content (% of Label Claim)
1	SAR-10-AM-C-001	95.96	96.53	97.79	99.05	97.12	98.29	98.34	97.76	99.22	97.30	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
2	SAR-10-AM-C-002	94.92	94.26	95.45	93.29	95.32	96.18	98.18	99.58	97.75	99.31	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
3	SAR-10-AM-C-003	99.67	87.63	95.49	86.61	100.06	100.70	98.12	94.27	95.79	96.06	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
4	SAR-10-AM-C-003	90.58	91.15	85.24	87.87	90.38	94.45	95.81	99.10	96.59	97.39	98.65	98.62	95.44	95.98	92.77	95.17	97.86	97.13	95.89	96.98	101.07	99.32	96.09
5	SAR-10-AM-C-004	97.37	100.05	102.49	110.69	106.43	109.41	102.44	86.66	102.40	87.74	102.09	105.86	105.99	98.41	101.91	99.21	104.70	103.43	97.16	97.95	94.81	102.04	101.91
6	SAR-10-AM-C-005	99.34	100.89	99.05	100.67	97.95	101.80	100.32	101.02	102.78	101.07	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
7	SAR-10-AM-C-006	104.02	105.71	100.63	97.25	101.42	98.25	103.38	101.05	99.42	102.50	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
8	SAR-10-AM-C-007	98.02	95.60	97.00	98.19	98.63	96.68	94.92	95.74	97.10	96.96	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
9	SAR-10-AM-C-008	80.66	87.43	91.96	85.04	84.65	89.29	85.19	88.61	87.56	86.03	80.52	86.84	85.56	94.86	91.01	87.33	91.07	93.67	90.60	90.49	93.32	93.65	87.20
10	SAR-10-AM-C-010	93.66	93.20	93.43	92.09	85.15	92.23	93.56	90.12	88.04	89.64	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
11	SAR-10-AM-C-011	100.80	92.44	97.45	98.13	98.28	99.32	97.13	99.46	97.59	98.77	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
12	SAR-10-AM-C-012	104.12	103.18	103.45	104.04	103.48	105.40	109.23	104.92	103.32	101.16	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
13	SAR-10-AM-C-012	102.86	102.76	103.04	104.52	103.07	106.04	102.52	106.36	79.23	101.09	102.84	98.77	102.76	105.18	100.00	100.94	100.93	102.83	99.63	102.61	98.09	100.20	101.02
14	SAR-10-AM-C-013	96.30	96.44	96.36	94.40	98.58	97.62	94.46	96.33	96.81	96.74	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
15	SAR-10-AM-C-014	94.51	95.19	94.03	91.40	97.01	95.69	95.89	95.28	94.18	94.21	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
16	SAR-10-AM-C-015	94.23	93.67	97.42	93.53	92.86	93.77	95.03	93.91	94.78	93.81	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
17	SAR-10-AM-C-016	98.65	100.15	97.13	98.44	97.61	96.79	97.91	98.66	99.25	99.85	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
18	SAR-10-AM-C-017	93.74	94.98	99.10	97.42	98.96	97.20	95.55	100.30	98.90	98.26	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
19	SAR-10-AM-C-017	96.89	102.69	95.08	96.25	98.04	98.32	97.58	95.61	97.05	96.87	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
20	SAR-10-AM-C-018	90.89	89.55	89.49	84.23	91.67	91.37	90.80	85.52	84.93	88.63	93.46	90.96	87.87	92.42	87.14	89.28	88.98	85.27	90.02	89.28	95.00	95.14	91.81
21	SAR-10-AM-C-019	101.76	100.71	100.55	100.39	99.52	102.61	101.27	102.38	100.00	101.42	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
22	SAR-10-AM-C-019	96.73	95.26	98.01	96.21	94.78	94.58	97.93	95.53	94.68	95.89	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
23	SAR-10-AM-C-020	89.07	93.00	86.32	91.43	88.02	87.73	97.91	90.43	85.67	88.95	90.25	81.53	90.03	88.74	86.05	86.87	85.46	90.87	82.74	91.44	86.25	83.91	77.06
24	SAR-10-AM-C-021	83.87	84.01	84.84	90.02	92.54	84.40	90.90	86.93	84.71	87.85	89.09	88.29	90.22	88.12	91.46	89.12	90.41	88.46	85.99	86.09	90.96	86.63	85.34
25	SAR-10-AM-C-022	94.65	99.50	97.70	98.93	99.04	96.33	100.30	98.73	99.33	97.97	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
26	SAR-10-AM-C-023	98.42	97.81	95.52	95.83	97.31	98.81	96.89	98.95	96.10	97.65	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
27	SAR-10-AM-C-024	99.55	99.85	101.61	98.43	98.66	97.88	97.29	97.63	102.77	95.56	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
28	SAR-10-AM-C-025	94.35	89.28	92.05	92.29	92.35	96.70	96.07	94.92	94.88	98.52	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
29	SAR-10-AM-C-026	100.30	99.52	104.26	97.82	95.28	103.06	97.44	97.77	104.61	109.22	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
30	SAR-10-AM-C-027	99.36	99.56	99.43	99.96	97.84	100.02	101.57	101.77	102.01	101.46	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
31	SAR-10-AM-C-027	101.13	97.59	101.60	97.23	100.00	99.71	95.14	97.07	99.32	94.68	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
32	SAR-10-AM-C-028	97.44	92.95	97.66	96.95	96.95	96.32	97.90	95.93	96.66	97.26	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
33	SAR-10-AM-C-028	84.42	94.30	91.12	96.47	93.96	93.62	93.70	89.60	95.30	93.49	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
34	SAR-10-AM-C-029	95.86	93.62	93.47	92.22	96.37	89.45	94.57	99.73	94.58	83.06	100.51	96.12	97.77	93.43	92.41	94.53	93.71	94.27	97.26	98.75	99.12	96.18	99.13
35	SAR-10-AM-C-030	104.12	96.28	90.60	98.91	98.06	98.25	101.88	99.63	95.57	99.44	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
36	SAR-10-AM-C-031	99.48	97.45	99.38	97.94	98.99	100.37	96.38	99.13	102.21	99.38	100.07	101.21	106.61	103.81	105.78	92.66	103.79	96.84	100.65	104.21	104.21	99.96	99.97
37	SAR-10-AM-C-032	104.75	101.45	100.61	96.28	87.49	91.03	104.12	101.95	91.02	95.79	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
38	SAR-10-AM-C-033	94.11	90.00	96.11	91.96	93.95	98.44	90.70	95.75	93.09	95.45	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
39	SAR-10-AM-C-034	95.77	91.25	88.77	92.99	94.41	95.33	93.80	95.99	94.52	94.37	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
40	SAR-10-AM-C-035	97.60	94.60	96.79	95.01	95.34	94.40	96.38	96.82	96.46	94.83	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
41	SAR-10-AM-C-037	99.82	96.31	78.95	98.72	97.27	100.59	98.49	99.33	102.50	100.21	92.69	89.46	94.72	93.79	96.36	96.62	92.31	93.51	90.70	92.44	90.62	89.95	91.38

No.	Sample Code	Unit 24 Content (% of Label Claim)	Unit 25 Content (% of Label Claim)	Unit 26 Content (% of Label Claim)	Unit 27 Content (% of Label Claim)	Unit 28 Content (% of Label Claim)	Unit 29 Content (% of Label Claim)	Unit 30 Content (% of Label Claim)	Mean Content (% of Label Claim) First Stage	Mean Content Second Stage	Acceptance Value (AV %) Tolerance: AV ≤ 15% First Stage	Acceptance Value Second Stage	Allowed Range First Stage Low Side M(1-0.01L2)	Allowed Range First Stage High Side M(1+0.01L2)	Allowed Range Second Stage Low Side M(1-0.01L2)	Allowed Range Second Stage High Side M(1+0.01L2)	First Stage	Second Stage	Final Judgment
1	SAR-10-AM-C-001	No Need	No Need	No Need	No Need	No Need	No Need	No Need	97.74	No Need	3.26	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
2	SAR-10-AM-C-002	No Need	No Need	No Need	No Need	No Need	No Need	No Need	96.42	No Need	7.27	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
3	SAR-10-AM-C-003	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.44	No Need	14.78	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
4	SAR-10-AM-C-003	98.43	96.30	97.24	97.79	92.17	96.25	94.05	92.86	95.39	16.43	10.22	73.88	123.13	73.88	123.13	Failed AV	Passed	Passed Second Stage
5	SAR-10-AM-C-004	105.59	98.19	101.40	95.09	96.64	91.55	99.30	100.57	100.30	19.50	11.15	75.43	125.71	75.22	125.37	Failed AV	Passed	Passed Second Stage
6	SAR-10-AM-C-005	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.49	No Need	3.36	No Need	75.37	125.61	No Need	No Need	Passed	No Need	Passed First Stage
7	SAR-10-AM-C-006	No Need	No Need	No Need	No Need	No Need	No Need	No Need	101.36	No Need	6.31	No Need	76.02	126.70	No Need	No Need	Passed	No Need	Passed First Stage
8	SAR-10-AM-C-007	No Need	No Need	No Need	No Need	No Need	No Need	No Need	96.88	No Need	4.50	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
9	SAR-10-AM-C-008	90.36	96.43	87.68	88.81	85.01	87.18	90.15	86.64	88.61	19.25	17.50	73.88	123.13	73.88	123.13	Failed AV	Failed AV	Failed Second Stage AV
10	SAR-10-AM-C-010	No Need	No Need	No Need	No Need	No Need	No Need	No Need	91.11	No Need	14.20	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
11	SAR-10-AM-C-011	No Need	No Need	No Need	No Need	No Need	No Need	No Need	97.94	No Need	5.90	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
12	SAR-10-AM-C-012	No Need	No Need	No Need	No Need	No Need	No Need	No Need	104.23	No Need	7.75	No Need	76.13	126.88	No Need	No Need	Passed	No Need	Passed First Stage
13	SAR-10-AM-C-012	99.68	99.95	95.62	97.84	97.42	94.85	99.10	101.15	100.39	18.89	9.75	75.86	126.44	75.29	125.49	Failed AV	Passed	Passed Second Stage
14	SAR-10-AM-C-013	No Need	No Need	No Need	No Need	No Need	No Need	No Need	96.40	No Need	5.13	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
15	SAR-10-AM-C-014	No Need	No Need	No Need	No Need	No Need	No Need	No Need	94.74	No Need	7.35	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
16	SAR-10-AM-C-015	No Need	No Need	No Need	No Need	No Need	No Need	No Need	94.30	No Need	7.22	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
17	SAR-10-AM-C-016	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.44	No Need	2.72	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
18	SAR-10-AM-C-017	No Need	No Need	No Need	No Need	No Need	No Need	No Need	97.44	No Need	6.09	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
19	SAR-10-AM-C-017	No Need	No Need	No Need	No Need	No Need	No Need	No Need	97.44	No Need	6.11	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
20	SAR-10-AM-C-018	101.24	92.62	94.25	94.83	94.28	88.40	90.53	88.71	90.66	16.52	15.08	73.88	123.13	73.88	123.13	Failed AV	Failed AV	Failed Second Stage AV
21	SAR-10-AM-C-019	No Need	No Need	No Need	No Need	No Need	No Need	No Need	101.06	No Need	2.42	No Need	75.80	126.33	No Need	No Need	Passed	No Need	Passed First Stage
22	SAR-10-AM-C-019	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.96	No Need	5.57	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
23	SAR-10-AM-C-020	87.21	87.40	80.55	87.94	84.76	75.54	81.51	89.85	86.82	17.30	20.96	73.88	123.13	73.88	123.13	Failed AV	Failed AV	Failed Second Stage AV
24	SAR-10-AM-C-021	86.98	85.30	91.49	87.38	85.06	82.78	85.14	87.01	87.48	19.14	16.39	73.88	123.13	73.88	123.13	Failed AV	Failed AV	Failed Second Stage AV
25	SAR-10-AM-C-022	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.25	No Need	4.27	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
26	SAR-10-AM-C-023	No Need	No Need	No Need	No Need	No Need	No Need	No Need	97.33	No Need	4.12	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
27	SAR-10-AM-C-024	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.92	No Need	5.08	No Need	74.19	123.65	No Need	No Need	Passed	No Need	Passed First Stage
28	SAR-10-AM-C-025	No Need	No Need	No Need	No Need	No Need	No Need	No Need	94.14	No Need	10.83	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
29	SAR-10-AM-C-026	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.93	No Need	10.25	No Need	75.70	126.16	No Need	No Need	Passed	No Need	Passed First Stage
30	SAR-10-AM-C-027	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.30	No Need	3.25	No Need	75.22	125.37	No Need	No Need	Passed	No Need	Passed First Stage
31	SAR-10-AM-C-027	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.35	No Need	5.87	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
32	SAR-10-AM-C-028	No Need	No Need	No Need	No Need	No Need	No Need	No Need	96.60	No Need	5.29	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
33	SAR-10-AM-C-028	No Need	No Need	No Need	No Need	No Need	No Need	No Need	92.60	No Need	14.22	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
34	SAR-10-AM-C-029	100.37	100.05	97.25	91.46	103.47	94.77	96.87	93.29	95.68	15.98	10.69	73.88	123.13	73.88	123.13	Failed AV	Passed	Passed Second Stage
35	SAR-10-AM-C-030	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.27	No Need	9.03	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
36	SAR-10-AM-C-031	No Need	No Need	No Need	No Need	No Need	No Need	No Need	99.07	No Need	3.84	No Need	74.30	123.84	No Need	No Need	Passed	No Need	Passed First Stage
37	SAR-10-AM-C-032	103.70	101.94	104.22	101.93	102.59	103.35	106.51	97.45	100.62	15.58	9.75	73.88	123.13	75.46	125.77	Failed AV	Passed	Passed Second Stage
38	SAR-10-AM-C-033	No Need	No Need	No Need	No Need	No Need	No Need	No Need	93.96	No Need	10.80	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
39	SAR-10-AM-C-034	No Need	No Need	No Need	No Need	No Need	No Need	No Need	93.72	No Need	10.13	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
40	SAR-10-AM-C-035	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.82	No Need	5.36	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
41	SAR-10-AM-C-037	93.11	91.07	92.67	93.56	93.41	90.05	90.79	97.22	94.05	17.24	13.74	73.88	123.13	73.88	123.13	Failed AV	Passed	Passed Second Stage

No.	Sample Code	Unit 1 Content (% of Label Claim)	Unit 2 Content (% of Label Claim)	Unit 3 Content (% of Label Claim)	Unit 4 Content (% of Label Claim)	Unit 5 Content (% of Label Claim)	Unit 6 Content (% of Label Claim)	Unit 7 Content (% of Label Claim)	Unit 8 Content (% of Label Claim)	Unit 9 Content (% of Label Claim)	Unit 10 Content (% of Label Claim)	Unit 11 Content (% of Label Claim)	Unit 12 Content (% of Label Claim)	Unit 13 Content (% of Label Claim)	Unit 14 Content (% of Label Claim)	Unit 15 Content (% of Label Claim)	Unit 16 Content (% of Label Claim)	Unit 17 Content (% of Label Claim)	Unit 18 Content (% of Label Claim)	Unit 19 Content (% of Label Claim)	Unit 20 Content (% of Label Claim)	Unit 21 Content (% of Label Claim)	Unit 22 Content (% of Label Claim)	Unit 23 Content (% of Label Claim)
42	SAR-10-AM-C-038	101.96	101.99	94.67	103.72	97.40	101.95	103.52	101.33	103.03	90.17	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
43	SAR-10-AM-C-039	96.43	93.67	95.68	95.95	95.68	96.41	97.66	96.89	98.04	95.18	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
44	SAR-10-AM-C-040	101.29	97.14	94.16	99.17	97.10	99.69	100.55	98.66	96.15	99.65	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
45	SAR-10-AM-C-040	95.86	92.86	94.76	94.79	91.09	92.22	92.89	92.15	91.97	93.88	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
46	SAR-10-AM-C-041	95.70	95.49	97.08	96.10	96.09	93.80	91.82	94.78	95.19	96.12	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
47	SAR-10-AM-C-042	99.21	98.72	96.67	102.10	96.99	103.25	95.66	98.52	101.02	96.06	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
48	SAR-10-AM-C-043	91.98	95.65	97.42	95.53	97.65	96.20	98.29	97.24	100.68	102.56	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
49	SAR-10-AM-C-044	106.94	101.02	103.87	102.48	100.11	103.80	104.75	104.11	106.30	98.54	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
50	SAR-10-AM-C-045	87.71	86.25	78.74	78.34	79.04	82.12	79.66	80.44	81.35	73.21	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
51	SAR-10-AM-C-047	97.48	101.28	97.89	102.17	90.62	104.24	104.87	103.79	96.77	97.26	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
52	SAR-10-AM-C-047	84.87	105.92	102.44	103.42	99.72	104.28	101.18	94.97	94.43	97.81	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
53	SAR-10-AM-C-048	102.79	97.41	97.57	98.11	98.54	99.75	99.37	93.31	98.47	97.27	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
54	SAR-10-AM-C-049	92.42	93.80	89.64	89.69	98.04	95.20	95.59	93.69	93.36	95.63	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
55	SAR-10-AM-C-050	92.08	94.50	93.71	90.21	88.98	95.65	91.16	99.57	97.59	100.05	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
56	SAR-10-AM-C-051	96.08	94.39	97.38	96.34	91.68	99.12	94.84	96.89	92.80	94.28	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
57	SAR-10-AM-C-052	82.11	86.35	74.25	83.59	79.66	75.33	80.46	80.53	83.35	88.22	81.12	82.17	79.39	78.89	77.47	72.31	83.92	80.18	81.85	81.29	91.30	94.00	91.99
58	SAR-10-AM-C-053	82.58	86.88	87.57	85.66	85.03	88.21	84.49	85.48	88.52	85.14	96.68	95.30	95.52	96.81	95.59	96.01	96.80	94.11	95.33	95.04	95.55	95.22	95.48
59	SAR-10-AM-C-054	101.27	101.23	100.98	99.51	100.80	99.81	98.26	92.95	98.48	94.66	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
60	SAR-10-AM-C-055	88.04	88.84	89.85	92.03	90.41	92.63	84.94	92.77	91.85	94.33	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
61	SAR-10-AM-C-056	99.08	102.46	102.42	97.29	99.92	100.54	101.98	100.10	99.48	101.66	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
62	SAR-10-AM-C-057	94.04	95.92	93.02	94.97	96.47	94.14	94.99	94.13	95.74	98.76	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
63	SAR-10-AM-C-057	91.72	93.14	93.00	91.25	93.76	94.86	94.81	95.38	92.74	94.60	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
64	SAR-10-AM-C-058	88.32	83.78	85.63	87.33	89.40	90.68	85.64	85.82	84.88	87.59	96.03	99.27	100.74	91.08	90.56	91.65	95.58	90.40	95.20	89.14	90.88	89.05	101.66
65	SAR-10-AM-C-059	100.64	104.54	99.61	97.52	101.69	87.53	100.78	88.82	105.80	103.15	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
66	SAR-10-AM-C-060	99.75	101.38	101.14	100.93	101.33	103.61	98.19	106.21	104.29	102.20	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
67	SAR-10-AM-C-061	102.47	103.83	101.59	99.01	101.00	97.45	102.61	100.41	100.65	101.52	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
68	SAR-10-AM-C-062	97.01	93.55	94.01	98.22	95.08	96.40	97.45	97.33	96.84	97.14	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
69	SAR-10-AM-C-063	103.74	103.83	98.42	103.97	98.00	105.13	94.77	97.28	101.64	104.51	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
70	SAR-10-AM-C-064	98.89	90.20	92.56	93.14	97.81	88.53	93.01	93.33	97.44	90.79	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
71	SAR-10-AM-C-066	88.93	88.56	86.31	88.60	87.63	82.47	84.16	82.33	86.04	83.54	92.85	87.06	83.62	88.76	93.58	77.07	92.11	83.13	85.66	81.84	84.27	93.06	91.36
72	SAR-10-AM-C-067	94.62	97.48	90.71	95.12	94.16	94.99	97.20	94.77	98.04	96.99	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
73	SAR-10-AM-C-068	102.55	100.34	99.67	101.59	101.20	102.26	100.35	100.17	97.86	98.81	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
74	SAR-10-AM-C-069	101.09	96.29	99.44	101.86	99.57	102.95	102.31	98.05	99.29	104.64	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
75	SAR-10-AM-C-070	94.20	94.22	95.64	94.02	96.86	95.91	94.05	93.94	95.22	96.64	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
76	SAR-10-AM-C-072	100.61	98.46	97.69	99.22	97.19	97.38	96.52	98.60	97.18	98.23	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
77	SAR-10-AM-C-074	93.89	95.93	96.34	94.63	95.88	96.05	93.06	95.64	96.91	97.15	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
78	SAR-10-AM-T-009	97.34	99.25	98.15	100.05	98.38	98.99	97.81	98.82	98.58	99.16	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
79	SAR-10-AM-T-009	97.83	99.60	98.22	99.37	95.59	98.86	97.43	98.47	98.34	98.54	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
80	SAR-10-AM-T-036	98.09	97.59	99.56	99.18	100.00	98.56	99.89	97.62	99.26	99.85	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
81	SAR-10-AM-T-036	98.93	99.88	98.35	98.52	96.29	98.29	99.54	98.10	98.26	96.37	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
82	SAR-10-AM-T-046	100.15	100.00	102.33	98.42	100.18	100.80	99.73	100.15	99.11	105.02	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need
83	SAR-10-AM-T-071	97.60	94.60	96.79	95.01	95.34	94.40	96.38	96.82	96.46	94.83	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need	No Need

No.	Sample Code	Unit 24 Content (% of Label Claim)	Unit 25 Content (% of Label Claim)	Unit 26 Content (% of Label Claim)	Unit 27 Content (% of Label Claim)	Unit 28 Content (% of Label Claim)	Unit 29 Content (% of Label Claim)	Unit 30 Content (% of Label Claim)	Mean Content First Stage	Mean Content Second Stage	AV First Stage	AV Second Stage	First Stage Low Side M(1-0.011L2)	First Stage High Side M(1+0.011L2)	Second Stage Low Side M(1-0.011L2)	Second Stage High Side M(1+0.011L2)	First Stage	Second Stage	Final Judgment
42	SAR-10-AM-C-038	No Need	No Need	No Need	No Need	No Need	No Need	No Need	99.98	No Need	10.75	No Need	74.98	124.97	No Need	No Need	Passed	No Need	Passed First Stage
43	SAR-10-AM-C-039	No Need	No Need	No Need	No Need	No Need	No Need	No Need	96.16	No Need	5.35	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
44	SAR-10-AM-C-040	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.36	No Need	5.40	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
45	SAR-10-AM-C-040	No Need	No Need	No Need	No Need	No Need	No Need	No Need	93.25	No Need	8.89	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
46	SAR-10-AM-C-041	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.22	No Need	6.85	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
47	SAR-10-AM-C-042	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.82	No Need	6.25	No Need	74.12	123.53	No Need	No Need	Passed	No Need	Passed First Stage
48	SAR-10-AM-C-043	No Need	No Need	No Need	No Need	No Need	No Need	No Need	97.32	No Need	8.13	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
49	SAR-10-AM-C-044	No Need	No Need	No Need	No Need	No Need	No Need	No Need	103.19	No Need	8.10	No Need	76.13	126.88	No Need	No Need	Passed	No Need	Passed First Stage
50	SAR-10-AM-C-045	No Need	No Need	No Need	No Need	No Need	No Need	No Need	80.68	No Need	27.67	No Need	73.88	123.13	No Need	No Need	Failed Deviation Range	No Need	Failed First Stage Deviation Range
51	SAR-10-AM-C-047	No Need	No Need	No Need	No Need	No Need	No Need	No Need	99.64	No Need	10.67	No Need	74.73	124.55	No Need	No Need	Passed	No Need	Passed First Stage
52	SAR-10-AM-C-047	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.91	No Need	14.98	No Need	74.18	123.63	No Need	No Need	Passed	No Need	Passed First Stage
53	SAR-10-AM-C-048	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.26	No Need	5.94	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
54	SAR-10-AM-C-049	No Need	No Need	No Need	No Need	No Need	No Need	No Need	92.71	No Need	12.29	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
55	SAR-10-AM-C-050	No Need	No Need	No Need	No Need	No Need	No Need	No Need	94.35	No Need	13.40	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
56	SAR-10-AM-C-051	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.38	No Need	8.46	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
57	SAR-10-AM-C-052	93.23	97.19	92.32	91.62	92.54	90.69	85.61	81.39	84.43	27.63	27.06	73.88	123.13	73.88	123.13	Failed AV	Failed Deviation Range	Failed Second Stage Deviation Range
58	SAR-10-AM-C-053	94.29	94.91	96.04	95.02	95.26	95.02	97.13	85.96	92.36	16.96	15.66	73.88	123.13	73.88	123.13	Failed AV	Failed AV	Failed Second Stage AV
59	SAR-10-AM-C-054	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.80	No Need	6.88	No Need	74.10	123.49	No Need	No Need	Passed	No Need	Passed First Stage
60	SAR-10-AM-C-055	No Need	No Need	No Need	No Need	No Need	No Need	No Need	90.57	No Need	14.56	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
61	SAR-10-AM-C-056	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.49	No Need	4.00	No Need	75.37	125.62	No Need	No Need	Passed	No Need	Passed First Stage
62	SAR-10-AM-C-057	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.22	No Need	7.16	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
63	SAR-10-AM-C-057	No Need	No Need	No Need	No Need	No Need	No Need	No Need	93.53	No Need	8.33	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
64	SAR-10-AM-C-058	95.96	90.26	99.82	101.07	99.70	90.97	88.75	86.91	91.89	16.75	17.24	73.88	123.13	73.88	123.13	Failed AV	Failed AV	Failed Second Stage AV
65	SAR-10-AM-C-059	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.01	No Need	12.17	No Need	75.01	125.01	No Need	No Need	Passed	No Need	Passed First Stage
66	SAR-10-AM-C-060	No Need	No Need	No Need	No Need	No Need	No Need	No Need	101.90	No Need	5.93	No Need	76.13	126.88	No Need	No Need	Passed	No Need	Passed First Stage
67	SAR-10-AM-C-061	No Need	No Need	No Need	No Need	No Need	No Need	No Need	101.05	No Need	4.41	No Need	75.79	126.32	No Need	No Need	Passed	No Need	Passed First Stage
68	SAR-10-AM-C-062	No Need	No Need	No Need	No Need	No Need	No Need	No Need	96.30	No Need	5.94	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
69	SAR-10-AM-C-063	No Need	No Need	No Need	No Need	No Need	No Need	No Need	101.17	No Need	8.76	No Need	75.88	126.46	No Need	No Need	Passed	No Need	Passed First Stage
70	SAR-10-AM-C-064	No Need	No Need	No Need	No Need	No Need	No Need	No Need	93.57	No Need	13.21	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
71	SAR-10-AM-C-066	85.92	94.17	90.82	87.06	86.37	82.00	85.14	85.86	86.81	18.83	19.92	73.88	123.13	73.88	123.13	Failed AV	Failed AV	Failed Second Stage AV
72	SAR-10-AM-C-067	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.41	No Need	8.26	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
73	SAR-10-AM-C-068	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.48	No Need	3.54	No Need	75.36	125.60	No Need	No Need	Passed	No Need	Passed First Stage
74	SAR-10-AM-C-069	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.55	No Need	5.98	No Need	75.41	125.69	No Need	No Need	Passed	No Need	Passed First Stage
75	SAR-10-AM-C-070	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.07	No Need	6.16	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
76	SAR-10-AM-C-072	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.11	No Need	3.25	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
77	SAR-10-AM-C-074	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.55	No Need	6.09	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
78	SAR-10-AM-T-009	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.65	No Need	1.87	No Need	73.99	123.32	No Need	No Need	Passed	No Need	Passed First Stage
79	SAR-10-AM-T-009	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.23	No Need	2.99	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
80	SAR-10-AM-T-036	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.96	No Need	2.24	No Need	74.22	123.70	No Need	No Need	Passed	No Need	Passed First Stage
81	SAR-10-AM-T-036	No Need	No Need	No Need	No Need	No Need	No Need	No Need	98.25	No Need	3.05	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage
82	SAR-10-AM-T-046	No Need	No Need	No Need	No Need	No Need	No Need	No Need	100.59	No Need	4.47	No Need	75.44	125.74	No Need	No Need	Passed	No Need	Passed First Stage
83	SAR-10-AM-T-071	No Need	No Need	No Need	No Need	No Need	No Need	No Need	95.82	No Need	5.36	No Need	73.88	123.13	No Need	No Need	Passed	No Need	Passed First Stage

Annex 1.6. Pharmacies information

No.	Pharmacy Type (I = Independent, C = Chain)	Pharmacy Code	Sample Code	District	Neatness	Sunlight on medicines	Air-conditioning	Availability of the "No Rx-Medicines w/o Rx" Sign	Seller Nationality	Seller Qualification	Request of Rx	Giving Instructions
1	I	SAR-10-PH-I-1179	SAR-10-AM-C-001	Al-Yarmouk	Excellent	Away	Excellent	No	Pakistan	Pharmacist	No	No
2	I	SAR-10-PH-C-0708	SAR-10-AM-C-002	Al-Hamra	Excellent	Partly Close	Excellent	No	Syria	Pharmacist	No	No
3	C	SAR-10-PH-C-0160	SAR-10-AM-C-003	Al-Dar Al-Baidaa	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
4	C	SAR-10-PH-C-0160	SAR-10-AM-C-003	Al-Dar Al-Baidaa	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
5	I	SAR-10-PH-I-0338	SAR-10-AM-C-004	Al-Rawda	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
6	C	SAR-10-PH-I-1103	SAR-10-AM-C-005	Al-Andalus	Excellent	Away	Excellent	No	Egypt/Jordan	Pharmacist	No	No
7	C	SAR-10-PH-C-1113	SAR-10-AM-C-006	Al-Khaleej	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
8	I	SAR-10-PH-C-0755	SAR-10-AM-C-007	Al-Nahda	Good	Away	Excellent	Yes	Egypt	Pharmacist	No	No
9	C	SAR-10-PH-C-1069	SAR-10-AM-C-008	Al-Nahda	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
10	I	SAR-10-PH-I-1018	SAR-10-AM-C-010	Al-Naseem (East)	Excellent	Away	Excellent	Yes	Jordan	Pharmacist	No	No
11	I	SAR-10-PH-I-1244	SAR-10-AM-C-011	Al-Naseem (West)	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
12	C	SAR-10-PH-C-0586	SAR-10-AM-C-012	Al-Naseem (West)	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
13	C	SAR-10-PH-C-0586	SAR-10-AM-C-012	Al-Naseem (West)	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
14	I	SAR-10-PH-I-0863	SAR-10-AM-C-013	Al-Naseem (West)	Excellent	Away	Good	Yes	Pakistan	Pharmacist	No	No
15	I	SAR-10-PH-I-0329	SAR-10-AM-C-014	Al-Naseem (West)	Good	Away	Good	Yes	Sudan	Pharmacist	No	No
16	C	SAR-10-PH-C-0412	SAR-10-AM-C-015	Al-Rawabi	Excellent	Away	Excellent	No	Sudan	Pharmacist	No	No
17	C	SAR-10-PH-C-0040	SAR-10-AM-C-016	Al-Rayyan	Excellent	Away	Excellent	Yes	Yemen	Pharmacist	No	No
18	I	SAR-10-PH-I-0949	SAR-10-AM-C-017	Al-Sa'ada	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
19	I	SAR-10-PH-I-0949	SAR-10-AM-C-017	Al-Sa'ada	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
20	I	SAR-10-PH-I-0247	SAR-10-AM-C-018	Al-Faihaa	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
21	C	SAR-10-PH-C-0121	SAR-10-AM-C-019	Al-Murooj	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
22	C	SAR-10-PH-C-0121	SAR-10-AM-C-019	Al-Murooj	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
23	C	SAR-10-PH-C-0877	SAR-10-AM-C-020	King Fahd	Excellent	Away	Excellent	Yes	Yemen	Pharmacist	No	No
24	C	SAR-10-PH-C-0898	SAR-10-AM-C-021	King Fahd	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
25	I	SAR-10-PH-I-0358	SAR-10-AM-C-022	Al-Nuzha	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
26	I	SAR-10-PH-I-1285	SAR-10-AM-C-023	Al-Falah	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
27	I	SAR-10-PH-I-0893	SAR-10-AM-C-024	Al-Waaha	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
28	C	SAR-10-PH-C-0998	SAR-10-AM-C-025	Al-Muhammadiyya	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
29	C	SAR-10-PH-C-0499	SAR-10-AM-C-026	Al-Wurood	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
30	I	SAR-10-PH-I-0704	SAR-10-AM-C-027	Al-Wazaaraat	Good	Away	Good	No	India	Pharmacist	No	No
31	I	SAR-10-PH-I-0704	SAR-10-AM-C-027	Al-Wazaaraat	Good	Away	Good	No	India	Pharmacist	No	No
32	C	SAR-10-PH-C-0100	SAR-10-AM-C-028	Al-Dubbat	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
33	C	SAR-10-PH-C-0100	SAR-10-AM-C-028	Al-Dubbat	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
34	I	SAR-10-PH-I-0124	SAR-10-AM-C-029	Al-Bat'ha	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
35	C	SAR-10-PH-C-0791	SAR-10-AM-C-030	Al-Ra'id	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
36	C	SAR-10-PH-C-0788	SAR-10-AM-C-031	Al-Rawdah	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
37	I	SAR-10-PH-C-0236	SAR-10-AM-C-032	Al-Nahda	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
38	I	SAR-10-PH-I-0839	SAR-10-AM-C-033	Al-Fouta	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
39	I	SAR-10-PH-I-0335	SAR-10-AM-C-034	Thulaim	Good	Away	Good	No	Egypt	Pharmacist	No	No
40	C	SAR-10-PH-I-0332	SAR-10-AM-C-035	Thulaim	Good	Away	Excellent	No	Egypt	Pharmacist	No	No
41	C	SAR-10-PH-C-0914	SAR-10-AM-C-037	Al-Aqeeq	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No

No.	Pharmacy Type (I = Independent, C = Chain)	Pharmacy Code	Sample Code	District	Neatness	Sunlight on medicines	Air-conditioning	Availability of the "No Rx-Medicines w/o Rx" Sign	Seller Nationality	Seller Qualification	Request of Rx	Giving Instructions
42	I	SAR-10-PH-I-1080	SAR-10-AM-C-038	Al-Naseem (West)	Good	Away	Excellent	Yes	Egypt	Pharmacist	No	No
43	I	SAR-10-PH-I-0099	SAR-10-AM-C-039	Al-Yamaama	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
44	I	SAR-10-PH-I-0930	SAR-10-AM-C-040	New Manfouha	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
45		SAR-10-PH-I-0930	SAR-10-AM-C-040	New Manfouha	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
46	C	SAR-10-PH-C-0258	SAR-10-AM-C-041	New Manfouha	Good	Away	Poor	Yes	Egypt	Pharmacist	No	No
47	C	SAR-10-PH-C-1166	SAR-10-AM-C-042	New Manfouha	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
48		SAR-10-PH-I-0816	SAR-10-AM-C-043	Manfouha	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
49	C	SAR-10-PH-C-1312	SAR-10-AM-C-044	New Manfouha	Good	Away	Excellent	No	Egypt	Pharmacist	No	No
50	C	SAR-10-PH-C-0422	SAR-10-AM-C-045	Al-Rabwa	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
51	C	SAR-10-PH-C-0655	SAR-10-AM-C-047	Al-Rabwa	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
52	C	SAR-10-PH-C-0655	SAR-10-AM-C-047	Al-Rabwa	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
53		SAR-10-PH-I-0270	SAR-10-AM-C-048	Al-Malazz	Good	Away	Good	Yes	Egypt	Pharmacist	No	No
54	C	SAR-10-PH-C-0401	SAR-10-AM-C-049	Al-Malazz	Good	Away	Good	Yes	Egypt	Pharmacist	No	No
55		SAR-10-PH-I-0615	SAR-10-AM-C-050	Al-Sulaymaniyya	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
56	C	SAR-10-PH-C-1289	SAR-10-AM-C-051	Al-Sulaymaniyya	Excellent	Away	Excellent	Yes	Yemen	Pharmacist	No	No
57	I	SAR-10-PH-I-0213	SAR-10-AM-C-052	Al-Sulaymaniyya	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
58		SAR-10-PH-I-0026	SAR-10-AM-C-053	Al-Sulaymaniyya	Excellent	Away	Good	No	Egypt	Pharmacist	No	No
59	C	SAR-10-PH-C-0104	SAR-10-AM-C-054	Al-Sulaymaniyya	Good	Away	Excellent	Yes	Egypt	Pharmacist	No	No
60		SAR-10-PH-C-1232	SAR-10-AM-C-055	Al-Sulaymaniyya	Good	Away	Excellent	No	Canadian	Pharmacist	No	No
61	C	SAR-10-PH-C-0502	SAR-10-AM-C-056	Al-Nasiriyya	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
62		SAR-10-PH-I-0645	SAR-10-AM-C-057	Al-Suwaidi	Good	Away	Excellent	Yes	Egypt	Pharmacist	No	No
63		SAR-10-PH-I-0645	SAR-10-AM-C-057	Al-Suwaidi	Good	Away	Excellent	Yes	Egypt	Pharmacist	No	No
64		SAR-10-PH-I-0079	SAR-10-AM-C-058	Dhahrat Al-Badi'ah	Good	Away	Good	No	Egypt	Pharmacist	No	No
65		SAR-10-PH-I-0676	SAR-10-AM-C-059	Al-Uraijaa (Center)	Good	Away	Good	Yes	Egypt	Pharmacist	No	No
66		SAR-10-PH-I-0459	SAR-10-AM-C-060	Al-Uraijaa (Center)	Good	Away	Good	Yes	Saudi	Pharmacist	No	No
67	C	SAR-10-PH-C-0993	SAR-10-AM-C-061	Al-Uraijaa (West)	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
68	C	SAR-10-PH-C-0718	SAR-10-AM-C-062	Al-Uraijaa (Center)	Good	Away	Good	Yes	Egypt	Pharmacist	No	No
69		SAR-10-PH-I-1001	SAR-10-AM-C-063	Tuwaiq	Good	Away	Good	Yes	Egypt	Pharmacist	No	No
70	C	SAR-10-PH-C-1303	SAR-10-AM-C-064	Al-Uraijaa (West)	Good	Away	Excellent	No	Egypt	Pharmacist	No	No
71		SAR-10-PH-I-0230	SAR-10-AM-C-066	Al-Badi'ah	Good	Away	Good	Yes	Egypt	Pharmacist	No	No
72		SAR-10-PH-I-1025	SAR-10-AM-C-067	Um Saleem	Good	Away	Good	No	India	Pharmacist	No	No
73	C	SAR-10-PH-C-0074	SAR-10-AM-C-068	Um Saleem	Good	Away	Good	Yes	India	Pharmacist	No	No
74	C	SAR-10-PH-C-1060	SAR-10-AM-C-069	Al-Quds	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
75	C	SAR-10-PH-C-0696	SAR-10-AM-C-070	Badr	Good	Away	Excellent	Yes	Egypt	Pharmacist	No	No
76	C	SAR-10-PH-C-1295	SAR-10-AM-C-072	Al-Shifaa	Excellent	Away	Excellent	Yes	Yemen	Pharmacist	No	No
77		SAR-10-PH-I-0959	SAR-10-AM-C-074	Al-Shumaisi	Good	Away	Poor	Yes	India	Pharmacist	No	No
78		SAR-10-PH-I-0939	SAR-10-AM-T-009	Al-Natheem	Excellent	Away	Excellent	No	Egypt	Pharmacist	No	No
79		SAR-10-PH-I-0939	SAR-10-AM-T-009	Al-Natheem	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
80		SAR-10-PH-I-0828	SAR-10-AM-T-036	Al-Amal	Good	Away	Excellent	No	India	Pharmacist	No	No
81		SAR-10-PH-I-0828	SAR-10-AM-T-036	Al-Amal	Good	Away	Excellent	No	India	Pharmacist	No	No
82	C	SAR-10-PH-C-0406	SAR-10-AM-T-046	Al-Rawabi	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No
83	C	SAR-10-PH-C-0239	SAR-10-AM-T-071	Al-Shifaa	Excellent	Away	Excellent	Yes	Egypt	Pharmacist	No	No

Chapter 2

Adherence of Community Pharmacies in Riyadh, Saudi Arabia, to Optimal Conditions for Keeping and Selling Good-Quality Medicines

Background

The quality of medicine is a global issue due to the ever increasing prevalence of counterfeit medicines worldwide.[1,2] Substandard medicines produced by legitimate manufacturers represent another threat as they may not contain the correct amount of active ingredients or may have manufacturing defects that alter their efficacy or make them dangerous for use.[3,4] On the other hand, even good quality medicines could be risky if they degrade due to poor storage or distribution conditions.[5,6]

This study is based on the results of the previous study (Chapter 1), which adopted the lot quality assurance sampling (LQAS) as a surveying technique to investigate the community pharmacies in Riyadh, Saudi Arabia, regarding the quality of medicines they sell.[7] It was conducted during a very hot season and amoxicillin was selected as an indicator of the quality of medicines in those pharmacies. The study reported substandard amoxicillin products in 13% of the randomly selected pharmacies. Although all samples were found to be authentic and the amount of the active ingredient was not dramatically low, it was below the lower limit of 90.0% according to the United States Pharmacopeia (USP), with the lowest amount being 80.7%. Manufacturing defects could not be ruled out but it was also suggested that degradation may have occurred to some samples due to poor storage or distribution conditions. That was supported by the finding that certain samples passed the quality test while other samples from the same batch, but purchased from other pharmacies, failed it.

Most medicines that can be kept on shelves must not be exposed to temperatures exceeding 25 °C. Excessive heat plays a major role in the degradation of various

medicines.[8,9] Similarly, temperature-controlled medicines must be handled carefully to avoid decomposition or degradation caused by excessive heat.[10]

The operational regulations of the system for private pharmaceutical facilities and products in Saudi Arabia contain several requirements for good storage and distribution of medicines.[11] According to this system, community pharmacies must have good air-conditioning systems that keep the temperature at $\leq 25\ ^{\circ}$ C and a thermometer for monitoring the temperature. Pharmacies must also have refrigerators with thermometers, and medicines must be kept away from sunlight. Floors and paints must be of materials that can be easily washed and cleaned. In addition, drug storage facilities must be equipped with automatic temperature recording systems that keep records for at least one year.

However, the criteria and quality of inspection and monitoring of the community pharmacies by the regulatory authorities may not be efficient. For example, one can easily buy prescription-only medicines, such as antibiotics, without a prescription despite the strict regulations.[7,12]

Objectives

This study explored the extent to which community pharmacies in Riyadh complied with the local regulations for keeping medicines until they are sold. It also explored the opinions of community pharmacists about the quality of medicines and tested their knowledge about the regulations.

This study was approved by the Ethical Committee of Kanazawa University and the Saudi Food and Drug Authority (SFDA).

Selection of Pharmacies

A list of all registered community pharmacies in Riyadh was obtained from the Saudi Ministry of Health (MOH) in August 2012 (1531 pharmacies). The calculated sample size of pharmacies was 181 according to the following formula:

$$n = z^2 N(1-p)/(z^2 p(1-p) + \xi^2 p^2 (N-1))$$

where n is the required sample size; z is the reliability coefficient (equals 1.96 at 95% confidence level); N is the population size; p is the probability of favorable outcome (set as 0.5); and ξ is set as 0.2 for the purpose of this study.

After all pharmacies were coded, the list was scrambled and 181+45 pharmacies were randomly selected from the list with MS Excel 2010 (Microsoft Co., USA). The additional 45 pharmacies were used as a reserve for an estimated dropout rate of 25% that may occur when a pharmacy is closed on the second visit, the pharmacy is out of business, or the pharmacy refuses to cooperate in the survey. The survey included 68 districts out of the 114 districts of Riyadh. The surveyed districts are sown in Annexes 2.1 and 2.2

Study Materials

The survey was conducted using a structured interview with the pharmacist in charge in each pharmacy, using three forms that were filled in by the interviewers. The

first form was a questionnaire while the second and third forms were used for inspection and observation purposes, respectively (Annexes 2.3–2.5).

Validity of the method was assessed on a sample of 33 pharmacies, not included in the study sample, and the Pearson correlation coefficient for internal reliability was 0.82.

The Interviewers

Thirty-four, fourth-year pharmacy students from King Saud University in Riyadh conducted the interviews between November 2 and November 23, 2012, after having attended a workshop followed by field training for a period of one week accompanied by the investigator. In-field follow-up and necessary support were provided by the investigator and one of the co-investigators. The training and survey schedule can be found in Annex 2.6.

The workshop started with an explanation of the survey objectives and a detailed presentation of the interview forms. It was followed by a discussion, where student questions were answered. The necessary communication skills were reviewed in brief since all students had already passed a course related to those skills.

The workshop was followed by a rehearsal of the interview, where all students played the role of the interviewer while the investigator played the role of the pharmacist. Notes were taken about each conversation and each student with a deficiency was offered more guidance and another rehearsal.

The final sample included 139 chain and 42 independent pharmacies, where a chain pharmacy belongs to a group of more than 3 pharmacies.[13] Twenty-one pharmacies were replaced because they were either closed on the second visit, out of business, or non-cooperative. The pharmacists in charge were all non-Saudi males and the summary of their background characteristics is shown in Table 2.1.

Table 2.1. Background characteristics of pharmacists.

Characteristics[a]	Value	
	Mean (years)	Range
Age	32	23–55
Total experience in community pharmacies	8.2	1–28
Experience in community pharmacies in Saudi Arabia	5.3	0.25–25
	Frequency ($n = 181$)	%
Qualification		
B.Sc	174	96.1
Pharm.D	4	2.2
M.Sc	2	1.1
Ph.D	1	0.6
Nationality		
Egypt	150	82.9
Yemen	7	3.8
Jordan	6	3.3
India	6	3.3
Sudan	5	2.8
Syria	3	1.7
Palestine	3	1.7
Pakistan	1	0.5
Position		
Manager	140	77.4
Staff	41	22.6

[a] All were males.

About 15% of the pharmacists said that they had not been informed about the system of community pharmacy practice in Saudi Arabia. Surprisingly, a significant percentage of pharmacists who knew the system gave wrong answers to simple questions related to the system. Table 2.2 summarizes the pharmacists' answers to such questions.

All pharmacists reported that they always receive the supply of medicines either directly from an official distributor or from a central store that belongs to the owner, or both. However, one independent pharmacy reported purchasing some medicines from a subagent. Nearly 56% of the pharmacists reported that they sometimes rejected some supplies of medicines because the temperature of the shipments may have exceeded 25 °C or because the packaging of the medicines was not intact upon receipt. When asked about the official distributors' facilities, 16% of the pharmacists said that the distributors' stores were substandard and 22% believed that the vehicles that were delivering the supply to the pharmacies were not suitable. In addition, 8% reported that they found some counterfeit products in their pharmacies and 46% reported that they had sometimes been contacted by illegal sellers offering known medicine brands at low prices. A significant percentage of the pharmacists reported that they found physicochemical changes in some of the medicines in their pharmacies; 16% noticed discoloration of some liquid medicines while 18.8% noticed wetting or solidification of powdered medicines. Sixty-seven percent of the pharmacists reported that they received complaints from their clients about subtherapeutic effects of some medicines. Only 64% said that they received memos from the drug regulatory authorities warning them of certain counterfeit or substandard products. Table 2.3 summarizes the pharmacists'

Table 2.2. Pharmacist knowledge about the local regulations of community pharmacy practice.

Aspects	Frequency $n = 181$ (%)
Were you informed about the community pharmacy regulations in Saudi Arabia?	
Yes	153 (84.5)
No	28 (15.4)
Are you requested to complete a certain number of continuing education hours every year?	
Yes, 60 hours[a]	49 (27.0)
Yes, incorrect number of hours	81 (44.8)
Not required	32 (17.7)
Don't know	19 (10.5)
Is it allowed to give free samples of over-the-counter medicines to clients?	
Yes	21 (11.6)
No[a]	155 (85.6)
Unsure	5 (2.8)
Except antibiotics, is it allowed to sell medicines by individual strips?	
Yes[a]	95 (52.4)
No	81 (44.8)
Unsure	5 (2.8)
Correct answers about some medicines that can be sold without a prescription	
Mild cough preparations	157 (86.7)
Topical disinfectants	143 (79.0)
Multivitamins	158 (87.3)
Topical burn preparations	139 (76.8)
Mild analgesics	167 (92.3)
Correct answers about some medicines that cannot be sold without a prescription	
Antihypertensive drugs	172 (95.0)
Mild oral antibiotics	138 (76.2)
Strong oral antibiotics	169 (93.4)
Antidiabetic drugs	166 (91.7)

a. The correct answer.

Table 2.3. Pharmacists' opinions on the adherence of their pharmacies and distributors to the regulations.

Aspects	Frequency $n = 181$ (%)
How often is the pharmacy temperature kept at ≤ 25 °C during working hours in hot seasons?	
100%	146 (80.7)
91–99%	12 (6.6)
81–90%	12 (6.6)
≤ 80%	9 (5.0)
Unsure	2 (1.1)
How often is the pharmacy temperature kept at ≤ 25 °C after working hours in hot seasons?	
100%	119 (65.7)
91–99%	15 (8.3)
81–90%	21 (11.6)
≤ 80%	19 (10.5)
Unsure	7 (3.9)
How often is the supply delivered to the pharmacy at a temperature of ≤ 25 °C in hot seasons?	
100%	102 (56.3)
91–99%	5 (2.8)
81–90%	11 (6.1)
≤ 80%	21 (11.6)
Unsure	42 (23.2)
How often is the supply received in intact packaging?	
100%	109 (60.2)
91–99%	41 (22.7)
81–90%	14 (7.7)
≤ 80%	8 (4.4)
Unsure	9 (5.0)
To what extent do you believe that the medicines in this pharmacy contain the correct amount of active ingredients?	
100%	71 (39.2)
91–99%	20 (11.1)
81–90%	36 (19.9)
≤ 80%	29 (16.0)
Unsure	25 (13.8)
To what extent do you believe that Riyadh pharmacies adhere to optimal storage conditions?	
100%	45 (24.8)
91–99%	21 (11.6)
81–90%	38 (21.0)
≤ 80%	46 (25.4)
Unsure	31 (17.2)
How often is the pharmacy inspected by the pharmacy regulatory authorities?	
Every 1–6 months	129 (71.3)
Every 7–12 months	19 (10.5)
Every 1–2 years	3 (1.6)
Unsure	30 (16.6)
The pharmacist noticed broken capsules or tablets inside packaged products in the pharmacy	53 (29.3)
The pharmacist noticed discoloration of some liquid medicines in the pharmacy	29 (16.0)
The pharmacist noticed wetting or solidification of powdered medicines in the pharmacy	34 (18.8)
Electricity blackout occurred during summer and pharmacy temperature raised above 25 °C	71 (39.2)[a]

a. Infrequent and lasts for 15–180 minutes.

opinions about the compliance of their pharmacies as well as their drug distributors with the local regulations.

In all pharmacies, excess medicines were stored in a small room inside each pharmacy. The inspection revealed serious problems regarding the temperature control in the pharmacies and in their refrigerators. Generally, the degree of cleanliness and neatness of pharmacies was considered acceptable since no serious breach was found. The recordings of inspections and observations made in each pharmacy are summarized in Table 2.4.

Various scoring systems were used in different studies concerned with the quality of pharmacies for a variety of statistical analyses.[14,15] In this study, however, when scores were added to key observations, no significant differences were found between the means of various independent factors, for example, chain vs. independent pharmacies, managers vs. staff, pharmacist informed about the regulations in Saudi Arabia vs. those not informed, and pharmacists aware of the continuing education requirements vs. those who were unaware. The analysis of variance is not possible within nationality and qualification groups because the number of candidates in some of these groups was very small compared to others. Also, no correlation is found between the scores and scale measures such as age and experience.

Table 2.4. Pharmacy inspection results and observations.

Elements	Frequency $n = 181$ (%)
Availability of an alternative power supply that covers the air-conditioning and refrigerator	10 (5.5)
Availability of an additional air-conditioner	147 (81.2)
Availability of a thermometer to measure pharmacy temperature	157 (86.7)
Pharmacy thermometer reading was $\leq 25\,°C$[a]	$n = 157$ 143 (91.1)
Availability of a refrigerator	179 (98.9)
Availability of a thermometer in the refrigerator	$n = 179$ 167 (93.3)
Refrigerator thermometer reading was $3–8\,°C$[b]	$n = 167$ 111 (66.5)
Walls behind medicine shelves were not struck by direct sunlight from the outside	136 (75.1)
Walls behind medicine shelves were not hot or warm	173 (95.6)
All medicines were not exposed to direct sunlight	160 (88.4)
Availability of at least 1 comprehensive drug information reference	37 (20.4)
Availability of a copy of the local regulations for community pharmacy practice	55 (30.4)
Free medicine samples were not seen	176 (97.2)
Medicine advertisement was not seen	153 (84.5)
There was a sign that states that prescription drugs cannot be sold without a prescription	158 (87.3)
Shelves were clean[c]	128 (70.7)
Walls were clean[c]	135 (74.6)
Floor was clean[c]	142 (78.5)
Floor was smooth/washable	181 (100)
Pharmacy was neatly organized (medicines were organized in shelves, shelves were organized in space, and pharmacy was not overcrowded with products)	147 (81.2)

a. Readings as high as 30 °C were observed in some pharmacies.
b. Readings as low as –10 and as high as 20 °C were observed in some pharmacies.
c. Free of dust, dirt, insects, or spider webs.

The findings of this study suggest that there were some deficiencies in the storage of medicines in community pharmacies in Riyadh and probably in the delivery vehicles, especially during hot seasons. This may, at least partly, explain the existence of substandard levels of amoxicillin in Riyadh pharmacies.[7] Even basic thermometers were not available in about 13% of pharmacies, and in about 9% of the pharmacies equipped with thermometers, the reading exceeded the 25 °C threshold. About 19% of pharmacies lacked a spare air-conditioner, making the quality of medicines questionable if the only available air-conditioner fails to operate optimally during summer. What is worse, some pharmacists reported that the air-conditioners may not have been kept running after working hours in hot seasons.

In addition, about 7% of refrigerators lacked thermometers, and in about 33% of refrigerators the temperatures were outside the accepted range. In about 25% of the pharmacies some walls behind medicine shelves were struck by direct sunlight from the outer side, and in about 4% of those pharmacies the walls felt warm.

The local regulations must be updated accordingly to ensure the best storage and distribution conditions for the medicines. Such detailed conditions and specifications may be obtained from the WHO.[16,17] The existence of an alternative power supply that covers the air-conditioning and refrigerators might be necessary in Riyadh although electricity blackouts are infrequent. However, if the durations of blackouts are enough to raise the temperature inside the pharmacy or the refrigerator above the allowed limits, then at least the refrigerator and one air-conditioning unit must be linked to an alternative power supply in each pharmacy.

A significant percentage of pharmacists were unaware of the basic regulations relating to community pharmacy practice. The striking issue is that having knowledge about the regulations had no impact on the quality of storage in the pharmacies. This may explain the absence of any correlation between age or experience and the general score achieved. This also explains the lack of any significant differences between various grouping factors relative to the mean scores.

Stricter, periodic monitoring and inspection by the authorities is highly recommended. It is suggested that all pharmacy owners must add spare air-conditioners as a prerequisite for licensing the pharmacies. Each pharmacy must be equipped with a room thermometer and refrigerator thermometer that keeps a record of temperature variation during the day. In addition, the pharmacy location must be in a position where its walls are not struck by direct sunlight from the outer side, or at least such walls must be adequately insulated. Medicine shelves must not be placed near the entrance or any location exposed to direct sunlight. Distributors' storage and delivery facilities must also be strictly monitored.

Finally, the continuing education program for community pharmacists must be closely monitored and supervised by the authorities. It is also recommended that passing an annual test about good pharmacy practice (GPP) should be a prerequisite for renewing the pharmacist license.

The quality of on-shelf medicines sold in community pharmacies in Riyadh may be questionable during hot seasons. Meanwhile, refrigerated medicines may not meet the quality standards throughout the entire storage time. More assertive measures and stricter monitoring of the adherence of the community pharmacies to good practice and good storage regulations are highly recommended. Community pharmacists' continuing education and knowledge about the practice regulations must be improved.

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Map of Saudi Arabia. Riyadh is represented by a red dot.

Map of Riyadh showing its districts. Surveyed districts are marked with red dots.

Annex 2.2. Pharmacy distribution table

No.	Pharmacy code	District	No.	Pharmacy code	District
1	1092	Al Nasiriyya	47	1252	Al Nahda
2	1000	Al Muaizliya	48	964	Al Masif
3	357	Al Uraija	49	860	Al Ulaya
4	121	Salahuddin	50	933	Al Muhammadiya
5	1417	Dharhrat Laban	51	937	Al Muhammadiya
6	1415	Dharhrat Laban	52	843	Al Ulaya
7	1403	Dharhrat Laban	53	847	Al Ulaya
8	203	Al Badi'ah	54	849	Al Ulaya
9	1382	Dirab	55	859	Al Ulaya
10	1428	Tuwaig	56	756	Al Uraija
11	126	Al Badi'ah	57	215	Al Badi'ah
12	946	Al Mursalat	58	178	Al Badi'ah
13	277	Al Hamra	59	754	Al Uraija
14	68	Al Quds	60	742	Al Uraija
15	282	Al Hamra	61	811	Al Azizia
16	94	Al Mughrizat	62	166	Al Iskan
17	285	Al Hamra	63	507	Al Zahra
18	1473	Qurtuba	64	1058	King Fahd
19	1478	Qurtuba	65	1024	Al Malaz
20	691	Al Shuhada	66	977	Al Masif
21	494	Al Rayyan	67	1470	Ghurnata
22	516	Al Salam	68	276	Al Hamra
23	515	Al Salam	69	367	Al Dira
24	491	Al Rayyan	70	303	Al Khuzama
25	194	Al Badi'ah	71	169	Al Andalus
26	553	Al Sulaimania	72	871	Al Ulaya
27	597	Al Suwaidi	73	418	Al Rawabi
28	772	Al Uraija	74	842	Al Ulaya
29	784	Al Uraija	75	225	Al Bat'ha
30	782	Al Uraija	76	876	Al Ulaya
31	728	Al Uraija	77	711	Al Sahafa
32	790	Al Uraija	78	408	Al Rabi
33	748	Al Uraija	79	898	Al Ghadir
34	737	Al Uraija	80	372	Al Raid
35	459	Al Rawda	81	257	Al Taawun
36	395	Al Rabwa	82	1440	Irqa
37	1240	Al Nafl	83	362	Al Diriya
38	1237	Al Nafl	84	1109	Al Nuzha
39	407	Al Rabi	85	702	Al Sahafa
40	735	Al Uraija	86	404	Al Rabi
41	732	Al Uraija	87	161	Al Izdihar
42	745	Al Uraija	88	1138	Al Naseem
43	144	Ishbilia	89	1140	Al Naseem
44	1330	Al Yarmmouk	90	693	Al Salihia
45	154	Ishbilia	91	1147	Al Naseem
46	1332	Al Yarmmouk	92	1170	Al Naseem

No.	Pharmacy code	District	No.	Pharmacy code	District
93	1126	Al Naseem	139	314	Al Khaleej
94	1146	Al Naseem	140	334	Al Khaleej
95	1171	Al Naseem	141	1443	Ulaisha
96	1040	Al Malaz	142	584	Al Suwaidi
97	1017	Al Malaz	143	622	Al Suwaidi
98	1049	King Fahd	144	596	Al Suwaidi
99	978	Al Masif	145	181	Al Badi'ah
100	1005	Al Malaz	146	678	Al Shumaisi
101	984	Al Masif	147	680	Al Shumaisi
102	218	Al Badi'ah	148	397	Al Rabwa
103	183	Al Badi'ah	149	524	Al Salam
104	347	Al Dar Al Baida	150	521	Al Salam
105	586	Al Suwaidi	151	426	Al Rawabi
106	3	Al Mansoura	152	386	Al Rabwa
107	672	Al Shifa	153	1285	Al Wuroud
108	645	Al Shifa	154	1335	Al Yarmmouk
109	641	Al Shifa	155	1323	Al Yarmmouk
110	620	Al Suwaidi	156	1318	Al Yarmmouk
111	659	Al Shifa	157	1116	Al Nuzha
112	274	Al Hamra	158	1294	Al Wuroud
113	1250	Al Nahda	159	1117	Al Nuzha
114	134	Ishbilia	160	1317	Al Yasameen
115	1244	Al Nahda	161	704	Al Sahafa
116	136	Ishbilia	162	1282	Al Wuroud
117	1270	Al Nahda	163	46	Al Sulayy
118	1242	Al Nahda	164	11	Al Mansoura
119	26	Al Yamama	165	9	Al Mansoura
120	100	Al Manakh	166	1518	Manfouha
121	422	Al Rawabi	167	27	Al Yamama
122	1068	King Faisal	168	957	Al Margab
123	991	Al Mathar	169	954	Al Margab
124	539	Al Sulaimania	170	1483	Manfouha
125	489	Al Rayyan	171	1525	Manfouha
126	447	Al Rawda	172	1491	Manfouha
127	48	Al Sulayy	173	955	Al Margab
128	485	Al Rawda	174	1480	Manfouha
129	104	Al Manar	175	1530	Namar
130	1076	King Faisal	176	1496	Manfouha
131	309	Al Khaleej	177	1455	Ghubaira
132	146	Ishbilia	178	1448	Ghubaira
133	1210	Al Naseem	179	1127	Al Naseem
134	1201	Al Naseem	180	1313	Al Washm
135	1211	Al Naseem	181	7	Al Mansoura
136	503	Al Rayyan			
137	313	Al Khaleej			
138	1204	Al Naseem			

Annex 2.3. The questionnaire and its Arabic translation

To: The community pharmacist in charge.

The objective of this questionnaire is to find out, through your experience and observation, whether community pharmacies in Saudi Arabia comply with the optimal practices that ensure keeping and selling good quality medicines. This will help regulatory authorities allocate resources appropriately for the improvement, which will eventually be reflected positively on the public health.

Your contribution is the cornerstone in our research and without it we will not be able to obtain the information in a better way. You have the right not to participate and you can quit the interview at any time if you feel that you do not want to continue.

You are a very important person to us!

We pledge not to disclose any personal information about you or your pharmacy in any published paper.

We hope that you share with us a few minutes to add your personal touch on this study.

Thank you.

The Chief Researcher
Hani M J Khojah
Mobile: 0505232584

( ) For interviewer only. Check when
1/7   the page is completely answered

1. Age (years)		Code:	SAR-12-PH-_____

2. Sex	☐ Male	☐ Female	

3. Nationality	☐ Saudi	☐ Egyptian	☐ Syrian
	☐ Sudanese	☐ Yemeni	☐ Jordanian
	☐ Pakistani	☐ Indian	☐ Other:_____

4. Qualification and country of each degree	☐ B.Sc. (_____)	☐ Pharm.D. (_____)	☐ M.Sc. (_____)
	☐ Ph.D. (_____)	☐ Other:_____(_____)	

5. Work experience in community pharmacies (years)	Total:_____ In this pharmacy:_____	In Saudi Arabia:_____	In Riyadh:_____
	In other areas (cities) of Saudi Arabia (area and years), if any:	Area:_____/_____years	Area:_____/_____years

6. Your position in this pharmacy	☐ Manager	☐ Assistant	☐ Other:_____

7. Were you informed about the regulations of community pharmacy practice in Saudi Arabia?	☐ Yes, after I was hired in Saudi Arabia	☐ Yes, before I was hired in Saudi Arabia	☐ Never

8. Are you requested to complete certain continuing education credit hours every year?	☐ Yes:_____hours	☐ No	☐ I do not know

9. Does this pharmacy belong to a chain of more than 3 pharmacies?	☐ Yes	☐ No	☐ I do not know

10. How often is this pharmacy temperature controlled (at less than or equal to 25° C) during working hours in hot seasons? (0–100%; 0=never, 100=always)	_____%	☐ I do not know	

( ) For interviewer only. Check when the page is completely answered

11. How often is this pharmacy temperature controlled (at less than or equal to 25° C) <u>after</u> working hours in hot seasons? (0–100%; 0=never, 100=always)

............................%   ☐ I do not know

12. Do you keep the air-conditioner running when the pharmacy is closed during hot seasons (including overnight)?

☐ Yes (always)   ☐ Yes (most of the times)   ☐ Yes (sometimes)

☐ No   ☐ I do not know

13. If this pharmacy has a separate store for keeping medicines, how often is the store temperature controlled (at less than or equal to 25° C) during hot seasons? (0–100%; 0=never, 100=always)

............................%   ☐ No separate store   ☐ I do not know

If the pharmacy has an alternative power supply, please answer the following questions:

14. Does it cover the air-conditioning system?

☐ No Air-conditioning   ☐ Yes   ☐ No
☐ I do not know

15. Does it cover the refrigerator?

☐ No refrigerator   ☐ Yes   ☐ No
☐ I do not know

16. Does it cover the separate store, if any?

☐ No separate store   ☐ Yes   ☐ No
☐ I do not know

17. Where does this pharmacy receive the supply of medicines from? you can check more than one answer if you have various sources

☐ I do not know   ☐ Directly from the manufacturer   ☐ From the official distributor of the medicine

☐ From a central store that belongs to several pharmacies   ☐ Other:............................

18. How often is the car/truck that supplies medicines to this pharmacy air-conditioned during hot seasons? (0–100%; 0=never, 100=always)

............................%   ☐ I do not know

(   ) For interviewer only. Check when the page is completely answered

3/7

19. How often do you receive the pharmacy supply of medicines in intact packaging? (0–100%; 0=never, 100=always)

.... %   ☐ I do not know

20. How often do you receive the pharmacy supply of medicines at less than or equal to 25° C during hot seasons? (0–100%; 0=never, 100=always)

.... %   ☐ I do not know

21. Have you ever rejected any supply of medicines because of poor packaging or because it was exposed to high temperature?

☐ Yes   ☐ No

---

22. When was the last time this pharmacy was inspected by a pharmacy regulatory authority?

☐ 0–6 months ago   ☐ 6–12 months ago   ☐ 1–2 years ago

☐ 2–3 years ago   ☐ More than 3 years ago   ☐ Never inspected since I was hired

---

If the pharmacy was inspected, please answer the following questions:

23. Who was the inspecting authority?

☐ Ministry of Health (MOH)   ☐ Saudi Food and Drug Authority (SFDA)   ☐ Other:...............

24. How often is this pharmacy inspected by a pharmacy regulatory authority?

☐ Every 0–6 months   ☐ Every 6–12 months   ☐ Every 1–2 years

☐ Every 2–3 years   ☐ Other:...............   ☐ I do not know

---

25. Is it allowed for this pharmacy to give free OTC samples to patients as gifts?

☐ Yes, all OTCs   ☐ Yes, some OTCs   ☐ No

☐ I do not know

---

26. Is it allowed to sell medicines by strip (except antibiotics) if the client was prescribed a few number of dosage units (less than a full box)?

☐ Yes   ☐ No   ☐ I do not know

( ) For interviewer only. Check when the page is completely answered

27. Have you ever encountered any of he following? You can check more than one answer.	☐ received complaints from patients about subtherapeutic effect of some medicines	☐ noticed poor distribution conditions by some distributors, especially during hot seasons	☐ noticed poor storage conditions in some distibutors' stores, especially during hot seasons
	☐ noticed poor storage conditions in some pharmacies, especially during hot seasons	☐ received a notification from a regulatory authority about the poor quality of certain medicines sold in pharmacies	

28. To what extent do you think that medicines sold in community pharmacies in Riyadh contain the correct amount of active ingredients (within the pharmacoepial range)? (0–100%; 0=never, 100=always)	............% ☐ I do not know
29. To what extent do you think that medicines sold in this pharmacy contain the correct amount of active ingredients (within the pharmacoepial range)? (0–100%; 0=never, 100=always)	............% ☐ I do not know
30. Have you ever received any notification from an official regulatory authority in Saudi Arabia about stopping selling a certain batch of a certain authentic medicine because it was of a poor quality?	☐ Yes ☐ No

(   ) For interviewer only. Check when the page is completely answered

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31. Have you ever received any notification from an official regulatory authority in Saudi Arabia about the existence of certain counterfeit medicines in the market?

☐ Yes   ☐ No

32. Has ever been a counterfeit medicine detected in this pharmacy, unintintionally?

☐ Yes   ☐ No

33. Have you ever encountered any of the following in this pharmacy? You can check more than one answer.

☐ Poor packaging of certain medicines   ☐ Broken capsules or tablets of certain medicines   ☐ Discoloration of certain medicines

☐ Precipitates in ceratin liquid medicines   ☐ Wet or solidified powder of certain medicines   ☐ Other changes:........
....
....

34. Have you ever received an offer from someone to buy and re-sell some medicines of known trade names but with very low price?

☐ Yes   ☐ No

35. To what extent do you think that community pharmacies in Riyadh adhere to the optimal storage conditions as required by the authorities (0–100%; 0=never, 100=always)

................%   ☐ I do not know

36. In previous hot seasons, did electricity blackouts happened so that the temperature inside this pharmacy raised above 25 °C?

☐ Yes   ☐ No   ☐ I do not know

37. If your answer was "yes", how many times/month such blackouts occur during hot seasons.

................times   ☐ I do not know

(   ) For interviewer only. Check when the page is completely answered

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38. If your answer was "yes", how long such blackouts take on average (in minutes)?	................................miutes	☐ I do not know	
39. Which of the following medicines can be sold without a prescription? You can check more than one answer	☐ Mild cough preparations	☐ Antihypertensives	☐ Disinfectants
	☐ Mild oral antibiotics	☐ Multivitamins	☐ Antidiabetics
	☐ Strong oral antibiotics	☐ Topical burn preparations	☐ Mild analgesics

( ) For interviewer only. Check when the page is completely answered

إلى: الصيدلي المسؤول في الصيدلية العامة

الهدف من هذه الاستبانة هو معرفة ما إذا كانت الصيدليات العامة في المملكة العربية السعودية تلتزم بالممارسات المثلى التي تضمن تخزين وبيع أدوية ذات جودة عالية، وذلك من خلال خبرتكم وملاحظاتكم. وهذا سيساعد الجهات المسؤولة في تخصيص الموارد بشكل ملائم من أجل التحسين، مما سينعكس في النهاية إيجابيًا على صحة المجتمع.

إن مساهمتك هي حجر الأساس في بحثنا وبدونها فإننا لن نستطيع الحصول على المعلومات بطريقة أفضل. وإن لك الحق في عدم المساهمة، كما أنه يمكنك أن تنسحب في أي وقت إذا شعرت بعدم الرغبة في الاستمرار.

أنت شخص مهم للغاية لنا!

ونحن نتعهد بعدم إفشاء أي معلومات شخصية عنك أو عن صيدليتك في أي بحث يتم نشره.

نأمل أن تشاركنا ببضع دقائق لكي تضع لمستك الخاصة على هذه الدراسة.

شكرًا لك.

الباحث الرئيس
هاني م. ج. خوجة
جوال: ٠٥٠٥٢٣٢٥٨٤

7/1

			١- السن (بالسنوات)
الرمز: SAR-12-PH-..............		....	

			٢- الجنس
	☐ أنثى	☐ ذكر	

			٣- الجنسية
☐ سوري	☐ مصري	☐ سعودي	
☐ أردني	☐ يمني	☐ سوداني	
☐ أخرى:.................	☐ هندي	☐ باكستاني	

			٤- المؤهل والدولة لكل درجة
☐ ماجستير (.............)	☐ فارم.د. (.............)	☐ بكالوريوس (...........)	
	☐ أخرى:.........(.........)	☐ دكتوراه (.............)	

			٥- الخبرة العملية في الصيدليات العامة (بالسنوات)
في الرياض:...............	في السعودية:.............	الإجمالي:....................	
		في هذه الصيدلية:.............	
المنطقة:.........../........سنة	المنطقة:.........../........سنة	في مناطق أو مدن أخرى في السعودية، إن وجد:	

			٦- مركزك في هذه الصيدلية
☐ أخرى:...................	☐ مساعد	☐ مدير	

			٧- هل تم إخطارك بنظام مزاولة المهنة في الصيدليات العامة في السعودية؟
☐ أبدًا	☐ نعم، قبل أن يتم تعييني في السعودية	☐ نعم، بعد أن تم تعييني في السعودية	

			٨- هل أنت مطالب بإتمام ساعات تعليم مستمر معينة كل سنة؟
☐ لا أعرف	☐ لا	☐ نعم ....ساعة	

			٩- هل تتبع هذه الصيدلية لسلسلة صيدليات يزيد عددها عن ٣ ؟
☐ لا أعرف	☐ لا	☐ نعم	

		١٠- ما هو مدى التحكم بدرجة حرارة هذه الصيدلية (بحيث تكون ٢٥ درجة مئوية أو أقل) خلال ساعات العمل في المواسم الحارة؟ (٠ – ١٠٠%؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)
☐ لا أعرف	.....................%	

١١- ما هو مدى التحكم بدرجة حرارة هذه الصيدلية (بحيث تكون ٢٥ درجة منوية أو أقل) خارج ساعات العمل في المواسم الحارة؟ (٠ – ١٠٠٪؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

☐ لا أعرف   %.....................

١٢- هل تبقي مكيف الهواء يعمل عندما تكون الصيدلية مغلقة أثناء المواسم الحارة (شاملا أثناء الليل)؟

☐ نعم (أحيانًا)   ☐ نعم (معظم الوقت)   ☐ نعم (دائمًا)

☐ لا أعرف   ☐ لا

١٣- إذا كان لهذه الصيدلية مستودع منفصل خارج الصيدلية لحفظ الأدوية، فما هو مدى التحكم بدرجة حرارته (بحيث تكون ٢٥ درجة منوية أو أقل) خلال ساعات العمل في المواسم الحارة؟ (٠ – ١٠٠٪؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

☐ لا أعرف   ☐ لا يوجد مستودع منفصل   %.....................

أجب عن الأسئلة التالية إذا كان للصيدلية مولد كهرباء احتياطي:

١٤- هل يغطي نظام تكييف الهواء؟
☐ لا   ☐ نعم   ☐ لا يوجد نظام تكييف
                              ☐ لا أعرف

١٥- هل يغطي الثلاجة؟
☐ لا   ☐ نعم   ☐ لا يوجد ثلاجة
                              ☐ لا أعرف

١٦- هل يغطي المستودع المنفصل، إن وجد؟
☐ لا   ☐ نعم   ☐ لا يوجد مستودع منفصل
                              ☐ لا أعرف

١٧- من أين تتلقى هذه الصيدلية تموينها من الأدوية؟ يمكنك اختيار أكثر من إجابة إذا كانت المصادر متعددة
☐ من الموزع الرسمي للدواء   ☐ مباشرة من المصنع   ☐ لا أعرف
☐ أخرى:.....................   ☐ من مستودع مركزي يتبع لعدة صيدليات

١٨- ما هو مدى كون السيارة التي توصل الأدوية لهذه الصيدلية مكيفة الهواء خلال المواسم الحارة؟ (٠ – ١٠٠٪؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

☐ لا أعرف   %.....................

3/7

١٩- ما هو مدى استلام الصيدلية لتموينها من الأدوية بحيث يكون تغليفها سليمًا؟ (٠ – ١٠٠%؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

......................% □ لا أعرف

٢٠- ما هو مدى استلام الصيدلية لتموينها من الأدوية في درجة حرارة تكون ٢٥ درجة مئوية أو أقل خلال المواسم الحارة؟ (٠ – ١٠٠%؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

......................% □ لا أعرف

٢١- هل سبق وأن قمت برفض أي تموين من الأدوية لأن التغليف كان سيئًا أو لأن الأدوية كانت متعرضة لحرارة عالية؟

□ نعم □ لا

٢٢- متى كانت آخر مرة تم فيها التفتيش على هذه الصيدلية من قبل جهة تنظيمية تعنى بشؤون الصيدلة؟

□ ٠–٦ أشهر سابقة □ ٦–١٢ شهرًا سابقًا □ ١–٢ سنة سابقة

□ ٢–٣ سنوات سابقة □ أكثر من ٣ سنوات سابقة □ لم يتم التفقد منذ أن تم تعييني

أجب عن الأسئلة التالية إذا سبق وأن تم التفتيش عل هذه الصيدلية:

٢٣- من كانت الجهة المفتشة؟   □ وزارة الصحة   □ الهيئة العامة للغذاء والدواء   □ أخرى:...................

٢٤- ما هي الفترة الزمنية التي يتكرر بعدها التفتيش على هذه الصيدلية عن طريق جهة تنظيمية تعنى بشؤون الصيدلة؟

□ كل ٠–٦ أشهر □ كل ٦–١٢ شهرًا □ كل ١–٢ سنة

□ كل ٢–٣ سنوات □ أخرى:................... □ لا أعرف

٢٥- هل يسمح لهذه الصيدلية أن تعطي عينات من الأدوية التي تصرف بدون وصفة كهدايا للزبائن؟

□ نعم، لجميع تلك الأدوية □ نعم، لبعض تلك الأدوية □ لا

□ لا أعرف

٢٦- هل يسمح ببيع الأدوية بالأشرطة (فيما عدى المضادات الحيوية) إذا كان عدد الوحدات الموصوفة أقل من العلبة الكاملة؟

□ نعم □ لا □ لا أعرف

			٢٧- هل صادفت أيًا من الآتي؟ يمكنك اختيار أكثر من إجابة
☐ لاحظت أن ظروف تخزين الأدوية سيئة في مستودعات بعض الموزعين، وبالذات خلال المواسم الحارة	☐ لاحظت أن توزيع الأدوية سيء من قبل بعض الموزعين، وبالذات خلال المواسم الحارة	☐ تلقيت شكاوى من بعض المرضى أن التأثير العلاجي لبعض الأدوية هو دون المستوى	
	☐ تلقيت إخطارًا من جهة رسمية يفيد برداءة جودة بعض الأدوية التي تباع في الصيدليات	☐ لاحظت أن ظروف تخزين الأدوية سيئة في بعض الصيدليات وبالذات خلال المواسم الحارة	

٢٨- إلى أي مدى تعتقد بأن الأدوية المباعة في الصيدليات العامة في الرياض تحتوي على الكمية الصحيحة من المواد الفعالة (في الحدود الدستورية المنصوص عليها)؟ (٠ – ١٠٠%؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

☐ لا أعرف   %.......................

٢٩- إلى أي مدى تعتقد بأن الأدوية المباعة في هذه الصيدلية تحتوي على الكمية الصحيحة من المواد الفعالة (في الحدود الدستورية المنصوص عليها)؟ (٠ – ١٠٠%؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

☐ لا أعرف   %.......................

٣٠- هل سبق وأن تلقيت إخطارًا من جهة رسمية في السعودية حول إيقاف بيع تشغيلة معينة من دواء أصلي بسبب رداءتها؟

☐ لا   ☐ نعم

٣١- هل سبق وأن تلقيت إخطارًا من جهة رسمية حول وجود أدوية مزيفة معينة في السوق؟

☐ نعم   ☐ لا

٣٢- هل تم اكتشاف وجود دواء مزيف في هذه الصيدلية من غير قصد لوجوده؟

☐ نعم   ☐ لا

٣٣- هل صادفت أيًا من الآتي في هذه الصيدلية؟ يمكنك اختيار أكثر من إجابة

☐ تغليفًا رديئًا لبعض الأدوية   ☐ كبسولات أو أقراص مكسورة لبعض الأدوية   ☐ تغيرًا في لون أدوية معينة

☐ ترسبات في بعض الأدوية السائلة   ☐ رطوبة أو تصلبًا في مسحوق أدوية معينة   ☐ تغيرات أخرى............ ....

٣٤- هل سبق وأن تلقيت عرضًا من شخص ما لشراء وإعادة بيع بعض أدوية ذات علامة تجارية معروفة ولكن بسعر منخفض جدًا؟

☐ نعم   ☐ لا

٣٥- إلى أي مدى تعتقد أن الصيدليات العامة في الرياض تلتزم بشروط التخزين المثلى المنصوص عليها نظامًا؟ (٠ ــ ١٠٠%؛ الصفر يعني لا يتم ذلك مطلقًا، المائة تعني دائمًا)

........................%   ☐ لا أعرف

٣٦- هل حدث انقطاع للتيار الكهربائي خلال المواسم الحارة السابقة بحيث ارتفعت درجة الحرارة داخل هذه الصيدلية إلى أكثر من ٢٥ درجة مئوية؟

☐ نعم   ☐ لا   ☐ لا أعرف

٣٧- إذا كانت إجابتك بنعم فكم مرة في الشهر تحدث مثل تلك الانقطاعات خلال المواسم الحارة؟

....................مرة   ☐ لا أعرف

		٣٨- إذا كانت إجابتك بنعم فكم دقيقة تستمر مثل تلك الانقطاعات على المتوسط؟
☐ لا أعرف	..................دقيقة	

☐ المطهرات	☐ خافضات ضغط الدم	☐ المستحضرات الخفيفة للسعال
☐ خافضات سكر الدم	☐ متعددات الفيتامين	☐ المضادات الحيوية الضعيفة التي تعطى بالفم
☐ المسكنات الخفيفة للألم	☐ المستحضرات الموضعية للحروق	☐ المضادات الحيوية القوية التي تعطى بالفم

٣٩- أي من الأدوية التالية يمكن بيعه بدون وصفة؟ يمكنك اختيار أكثر من إجابة

Annex 2.4. The inspection form and its Arabic translation

Observation form A

Code:	SAR-12-PH-...................	Interview date: ..../........./ 2012

Interview starting time (hours:minutes):	..........:..........	☐ am	☐ pm

Additional air-conditioning unit	☐ Available	☐ Not available	

Pharmacy Thermometer	☐ Available and working. Reading is .... °C ☐ Not available	☐ Available but not working	☐ Available as claimed by the pharmacist but not allowed to see

Separate-store Thermometer	☐ Available and working. Reading is .... °C ☐ Not available	☐ Available but not working ☐ No separate store	☐ Available as claimed by the pharmacist but not allowed to see

Refrigerator	☐ Available and working. Reading (if any) is .... °C ☐ Available as claimed by the pharmacist but not allowed to see	☐ Available, working, but without a thermometer ☐ Not available	☐ Available but not working

Alternative power supply	☐ Available and seen	☐ Available as claimed by the pharmacist but not allowed to see	☐ Not available

Inside walls behind medicine shelves (walls that are struck by sunlight from outside)	☐ Hot ☐ No such situation	☐ Warm	☐ Cool/cold

( ) For interviewer only. Check when
1/2   the page is completely answered

Pharmacy references provided by the owner	☐ Not allowed to see	☐ Nothing available	Reference 1: .... Publishing year: ....
	Reference 2: .... Publishing year:	Reference 3: .... Publishing year:	Reference 4: .... Publishing year: ....
Regulations of community pharmacy practice in Saudi Arabia	☐ Available	☐ Available as claimed by the pharmacist but not allowed to see	☐ Not available
Pharmacy phone number (from the pharmacist not from the sign of the pharmacy)	....		
Interview ending time (hours:minutes):	.... :	☐ am	☐ pm

( ) For interviewer only. Check when
2/2   the page is completely answered

Observation form A

تاريخ المقابلة: ..../............/ ٢٠١٢		SAR-12-PH-...............	الرمز:

☐ بعد الظهر	☐ صباحًا	.... :	وقت بداية المقابلة (دقائق:ساعات):

	☐ غير موجود	☐ موجود	مكيف الهواء الإضافي

☐ موجود كما قال الصيدلي ولكن لم يسمح لي برؤيته	☐ موجود ولكن لا يعمل	☐ موجود ويعمل. قراءته........درجة مئوية	مقياس درجة حرارة الصيدلية
		☐ غير موجود	

☐ موجود كما قال الصيدلي ولكن لم يسمح لي برؤيته	☐ موجود ولكن لا يعمل	☐ موجود ويعمل. قراءته........درجة مئوية	مقياس درجة حرارة المستودع المنفصل
☐ لا يوجد مستودع منفصل		☐ غير موجود	

☐ موجودة ولكن لا تعمل	☐ موجودة وتعمل ولكن بدون مقياس درجة حرارة	☐ موجودة وتعمل. قراءتها........درجة مئوية	الثلاجة
	☐ غير موجودة	☐ موجودة كما قال الصيدلي ولكن لم يسمح لي برؤيتها	

☐ غير موجود	☐ موجود كما قال الصيدلي ولكن لم يسمح لي برؤيته	☐ موجود ورأيته	مولد الكهرباء الاحتياطي

☐ عادية/باردة	☐ دافئة	☐ حارة	الجدران الداخلية خلف الأدوية (الجدران التي تضربها الشمس من الخارج)
		☐ لا توجد مثل هذه الجدران	

			مراجع الصيدلية التي يوفرها مالك الصيدلية
المرجع ١	☐ غير موجودة	☐ لم يسمح لي برؤيتها	
....			
سنة النشر:			

المرجع ٤	المرجع ٣	المرجع ٢	
....	....	....	
سنة النشر:	سنة النشر:	سنة النشر:	

			نظام مزاولة المهنة في الصيدليات العامة
☐ غير موجود	☐ موجود كما قال الصيدلي ولكن لم يسمح لي برؤيته	☐ موجود	

رقم هاتف الصيدلية (يؤخذ من الصيدلي وليس من لوحة الصيدلية)

....

وقت نهاية المقابلة (دقائق:ساعات): .... : .... ☐ صباحًا ☐ بعد الظهر

Annex 2.5 The observations form and its Arabic translation

Observation form B

Pharmacy code:	SAR-12-PH-................	**Interview date:**	.............../.............../ 2012
Pharmacy name:	....	**Address:**	....

Air-conditioning during the interview	☐ Working and efficient	☐ Working but inefficient	☐ Not working
Sunlight	☐ Away from all medicines	☐ Close to all/some medicines	
Free medicine samples	☐ Observed. Names:	☐ Not observed	
Medicine advertisement	☐ Observed. Names:	☐ Not observed	
The sign that states that prescription-only medicines are not sold without a prescription	☐ Available	☐ Not available	
Shelves cleanliness (you can check more than one answer except when you check "Clean")	☐ Clean ☐ Insects ☐ Other:...............	☐ Dust ☐ Dirt spots ☐ Other:...............	☐ Spider webs ☐ Other:............... ☐ Other:...............
Wall cleanliness (you can check more than one answer except when you check "Clean")	☐ Clean ☐ Insects ☐ Other:...............	☐ Dust ☐ Dirt spots ☐ Other:...............	☐ Spider webs ☐ Other:............... ☐ Other:...............

1/2

(   ) For interviewer only. Check when the page is completely answered

Pharmacy floor. You can check more than one answer. It could be smooth/washable but not clean or smooth/washable and clean.	☐ Clean	☐ Smooth/washable	☐ Dust
	☐ Insects	☐ Dirt spots	☐ Other:...................
	☐ Other:...................	☐ Other:...................	☐ Other:...................
Organization of items in the pharmacy (you can check more than one answer except when you check "Neat")	☐ Neat	☐ Shelves not well distributed in the pharmacy	☐ Medicines not organized in shelves
	☐ Pharmacy is overcrowded with products that occupy the space	☐ Other:...................	☐ Other:...................

( ) For interviewer only. Check when the page is completely answered

Observation form B

تاريخ المقابلة: /_____/ ٢٠١٢		الرمز SAR-12-PH-........................
العنوان:		اسم الصيدلية: ....

تكييف الهواء أثناء المقابلة	☐ يعمل بكفاءة	☐ يعمل ولكن ليس بكفاءة	☐ لا يعمل
ضوء الشمس	☐ بعيد عن كل الأدوية	☐ قريب من كل أو بعض الأدوية	
العينات المجانية للأدوية	☐ لوحظت، أسماؤها هي:	☐ لم تلاحظ	
الدعاية للأدوية	☐ لوحظت، أسماؤها هي:	☐ لم تلاحظ	
اللوحة التي تنص على عدم جواز بيع الأدوية الوصفية إلا بوصفة طبية	☐ موجودة	☐ غير موجودة	
نظافة الرفوف (يمكنك اختيار أكثر من إجابة إلا إذا كان اختيارك "نظيفة")	☐ نظيفة	☐ غبار	☐ نسيج عنكبوت
	☐ حشرات	☐ بقع غير نظيفة	☐ أخرى:................
	☐ أخرى:................	☐ أخرى:................	☐ أخرى:................
نظافة الجدران (يمكنك اختيار أكثر من إجابة إلا إذا كان اختيارك "نظيفة")	☐ نظيفة	☐ غبار	☐ نسيج عنكبوت
	☐ حشرات	☐ بقع غير نظيفة	☐ أخرى:................
	☐ أخرى:................	☐ أخرى:................	☐ أخرى:................

			أرضية الصيدلية. يمكنك اختيار أكثر من إجابة. قد تكون ملساء قابلة للغسل ولكن غير نظيفة. وقد تكون ملساء قابلة للغسل ونظيفة.
☐ غبار	☐ ملساء قابلة للغسل	☐ نظيفة	
☐ أخرى:	☐ بقع غير نظيفة	☐ حشرات	
☐ أخرى:	☐ أخرى:	☐ أخرى:	

			ترتيب المواد في الصيدلية (يمكنك اختيار أكثر من إجابة إلا إذا كان اختيارك "أنيقة")
☐ الأدوية غير مرتّبة في الرفوف	☐ الرفوف غير موزعة بشكل جيد	☐ أنيقة	
☐ أخرى:	☐ أخرى:	☐ الصيدلية مكتظة بالمنتجات التي تحتّل المساحة	
....	....		
....	....		

Annex 2.6 Training and survey schedule

	Nov 2	Nov 3	Nov 4	Nov 5	Nov 6	Nov 7	Nov 8	Nov 9	Nov 17	Nov 18	Nov 19	Nov 20	Nov 21	Nov 22	Nov 23
Group 1 5 Students 26 Pharmacies	Workshop for all students and rehearsal	Field Training + Survey	Survey →						→						
Group 2 5 Students 26 Pharmacies			Field Training + Survey	Survey →						→					
Group 3 5 Students 26 Pharmacies				Field Training + Survey	Survey →						→				
Group 4 5 Students 26 Pharmacies					Field Training + Survey	Survey →						→			
Group 5 5 Students 26 Pharmacies						Field Training + Survey	Survey →						→		
Group 6 5 Students 26 Pharmacies							Field Training + Survey	Survey →						→	
Group 7 4 Students 25 Pharmacies								Field Training + Survey → Survey							→