Islamic Republic of Afghanistan
Ministry of Public Health
National Medicines and Food Board
Medicines Quality Assurance Subcommittee

TECHNICAL REPORT

Implementation of GPHF-Minilab Pilot in Afghanistan

November 2015

CONTENTS

ACRONYMS

ANPA	Afghanistan National Pharmacists Association
EML	Essential medicine list
FDQCD	Food and Drug Quality Control Directorate
FTE	Full-time equivalent
GDPA	General Directorate of Pharmaceutical Affairs
GPHF	Global Pharma Health Fund
HLIED	Health Legislation Implementation Ensuring Directorate
INN	International nonproprietary name
ITA	International technical advisor
M&E	Monitoring and evaluation
MoPH	Ministry of Public Health
NMRA	Medicines regulatory authority
MSH	Management Science for Health
NGO	Nongovernmental organization
NMFB	National Medicines and Food Board
QASC	Quality Assurance Subcommittee
QC Lab	Quality Control Laboratory
SOP	Standard operating procedure
SPS	Strengthening Pharmaceutical Services
TLC	Thin-layer chromatography
USAID	US Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

ACKNOWLEDGMENTS

The Ministry of Public Health (MoPH) of the Islamic Republic of Afghanistan gratefully acknowledges the contribution of all those who made the pilot study of Global Pharma Health Fund Minilab® (GPHF-Minilab) possible in Afghanistan. This pilot study ascertains, amidst formidable challenges that the health sector faces, that the robust local competency is evolving in the country to underpin development of a medicines quality assurance system. It also adds to the trust of the health sector reform, including the creation of a national medicines regulatory authority as the means to attaining universal access to essential medicines of good quality.

The pilot study was coordinated, compiled and edited by MoPH staff and its key stakeholders—

- Pharmacist Mohammad Omar Mansory, Registration and License Issuing Manager, General Directorate of Pharmaceutical Affairs (GDPA)
- Pharmacist Mohammad Junaid Nimati, Afghanistan National Pharmacists Association (ANPA)
- Pharmacist Mohammad Zafar Barai, Health Legislation Implementation Ensuring Directorate (HLIED)
- Professor Qand Agha Nazari, Faculty of Pharmacy, University of Kabul
- Pharmacist Mirza Muhammad Ayoubi, Afghan National Standard Authority
- Pharmacist Aamena Rustaqi, Quality Control Labs, MoPH
- Dr. Safiullah Nadeeb, World Health Organization (WHO)
- Pharmacist Nematullah Nawrozian, Technical Advisor Medicines Affairs, MoPH National Medicines and Food Board (NMFB)
- Pharmacist Noor Ahmad Zulal, Quality Assurance Consultant, GDPA

Technical advisors who cooperated in development of this report as and oversight bodies are:

- Pharmacist Mohammad, Zafar Omari, SPS/CoP
- Pharmacist Mohammad Basir, SPS/Supply Chain System Advisor
- Pharmacist Jamshed Noori, SPS Quality Assurance Officer
- Pharmacist Sayed Murtaza Sadaat, SPS Quality Assurance Office
- Professor Elirilingana Kaale, Minilab Consultant in Tanzania

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Ph. Abdul Hafiz Quraishi
Director General for pharmaceutical affaires
Kabul, Afghanistan

EXECUTIVE SUMMARY

Background Information

One of the biggest challenges developing countries face in their fight against counterfeit and substandard medicines is building their technical capacity to regulate medicines. Without effective and affordable analytical technologies, the quality of the medicines cannot be secured in the country. Global Pharma Health Fund Minilab® (GPHF-Minilab) kit is one widely deployed field adapted technology used in many developing countries. Despite the potential of the GPHF-Minilab kit, it has not been formally adopted as a first-line screening technique in the Islamic Republic of Afghanistan. This study aimed to explore the potential applicability by implementing a pilot product screening using GPHF-Minilab kit for samples collected from selected public and private facilities in Afghanistan.

To implement the recommendations for improving medicines quality and safety, the Ministry of Public Health (MoPH) decided to develop a national strategy for medicines quality assurance, which included piloting a risk-based sampling and screening activity with GPHF-Minilab kits for a number of medicines in selected provinces and for imported medicines, to screen for potential counterfeit and/or grossly substandard products.

The GPHF-Minilab kit is a portable medicine screening kit used in several developing countries. The kit can be carried to any place or point in the supply chain for normal laboratory testing, and it is approved by the World Health Organization (WHO) and the United States Pharmacopeia (USP). More than 680 GPHF-Minilab kits have been supplied and used across 90 different countries.

Methods

A cross-sectional study was designed to collect medicine samples from public and private facilities (e.g., retail pharmacies, wholesale pharmacies, and importers, private and governmental hospitals). Prior to testing, training materials and survey protocols were developed to guide the implementation of the pilot phase. Target medicines and provinces (Balkh, Herat, Kabul, Kandahar, Kunduz, and Nangarhar) were purposefully selected. The GPHF-Minilab screening was performed at two locations: 1) the Food and Drug Quality Control Directorate of MoPH and 2) the Faculty of Pharmacy, Kabul University. Each collected sample was subjected to Tier 1 testing using GPHF-Minilab; physical inspection, disintegration, verification of content, and identification by Thin-layer chromatography (TLC); and following specific standard operating procedures (SOPs) and protocols. Samples that failed GPHF-Minilab testing were classified as failed at basic quality testing and were referred to Tier 2. In addition, about 4 percent of passing samples were also referred to Tier 2 to confirm Tier 1 test results.

Results

Training stations were established at the Faculty of Pharmacy, Kabul University. A competence-based training package with more than 75 percent hands-on training was developed and successfully conducted. A total of 25 key staff participated: four representing the General Directorate for Pharmaceutical Affairs (GDPA), four from the Food and Drug Quality Control Directorate (FDQCD), two from the Health Legislation Implementation Ensuring Directorate (HLIED), four from the Faculty of Pharmacy of Kabul University, six from the Quality Assurance Subcommittee (QASC), two from the Monitoring and Evaluation (M&E) Directorate of MoPH, and three from the Strengthening Pharmaceutical Systems (SPS) project.

Out of 191 samples, 98 (51.3 percent) were collected from private facilities while 93 (48.7 percent) came from public facilities. The majority of dosage forms studied were tablets (152, or 79.6 percent), 27 (14.1 percent) were capsules, and 12 (6.3 percent) were injectable solutions. About half of the total medicines collected were antibiotics (44 percent) followed by analgesics (18.8 percent); the rest were less than 10 percent each; Two tiers of testing found similar percentages of failing medicines (6 percent and 4.2 percent, respectively). The overall passing rate was 95.8 percent (183/191) and failure rate was 4.2 percent (8/191). The results showed that the average sample analysis time was 1.5 hours per full-time equivalent (FTE) analyst.

Concluding Remarks

A competent expert team was created at MoPH and Kabul University and provided with training materials that will ensure sustainability of such training in the future with reduced dependence on international technical advisors (ITAs). Various documents were developed to guide the implementation of the pilot GPHF-Minilab project. The GPHF-Minilab screening test is relatively inexpensive, rapid, and provides a simple and accurate assessment of drug quality; it has an important role to play in the monitoring of medicine quality in resource-poor and rural settings such as Afghanistan. The short screening time achieved per sample per FTE indicates that the technology has untapped potential for deployment as a preliminary screening to reduce the number of samples sent to the central lab for full monograph testing.

Recommendations

Following the successful pilot implementation of the GPHF-Minilab in a scenario that mimics a post-marketing surveillance and testing of the pharmaceutical products circulating in Afghanistan, this study recommends the dissemination of study findings to a wider stakeholder audience, and adoption of this technology to strengthen quality assurance in the medicine procurement process. In particular, all products entering Afghanistan at all major ports of entry should be screened according to the tiered approach prescribed in the recently approved Afghanistan National Pharmaceutical Quality Assurance Policy. However this should be preceded by stakeholder consultation to cultivate buy-in as the process evolves.

1. INTRODUCTION

Medicine product quality and integrity have been identified as major concerns in several countries, especially in developing countries where assessments were performed.[1] Since pharmaceuticals frequently are very expensive and therefore prone to counterfeiting and substandard production, the establishment of a viable and sustainable market protection through regulatory processes is essential. These processes must be capable of detecting unacceptable products to help provide a deterrent to unscrupulous manufacturers and suppliers.

Adequate medicines legislation and regulations, a competent medicines regulatory authority (MRA), and appropriate medicine information are required to ensure the safety, efficacy, and quality of medicines.[2] All MRA functions must work in concert to provide effective public health protection.

One of the biggest challenges developing countries face in their fight against counterfeit and substandard medicines is building their technical capacity to regulate medicines. Without effective and affordable analytical technologies, the quality of the medicines cannot be secured in the country. In response to this need, the World Health Organization (WHO) and the United States Pharmacopeia (USP) has supported the use of a portable medicine screening kit in several developing countries. Developed by the Global Pharma Health Fund (GPHF), the kit is called GPHF-Minilab®.

Overall, more than 680 GPHF-Minilab Kits have been supplied and used across 90 different countries worldwide in resource-limited settings as a screening test for counterfeit and substandard medicines.[3] [4]

Previous studies of the pharmaceutical sector of Afghanistan provide some insight into the medicine supply situation in the country. The Strengthening Pharmaceutical Systems (SPS) project's surveys established the existing capacities for the medicines regulation and control framework.

Early in 2013, the National Medicines and Food Board (NMFB) with the technical support of SPS project forwarded the GPHF-Minilab pilot proposal to the ministry of public health, who referred the issue to the Food and Drug Quality Control Directorate (FDQCD) for review, comments, and recommendations. In spite of the extensive documentation provided by SPS, the FDQCD failed to appreciate the possible benefits of the GPHF-Minilab for the overall quality assurance system. In a meeting an extensive debriefing on the GPHF-Minilab was given to the Deputy Minister on May 13, 2014. The deputy minister agreed that the GPHF-Minilab can be used to test samples for importing companies, wholesale pharmacies, retail pharmacies, specialist hospitals, regional hospitals, and warehouses, and for general Quality Control Laboratory (QC Lab) use and pharmacist training institutions. Site selection was referred to the Quality Assurance Subcommittee (QASC), which identified and recommended the Ministry of Public Health (MoPH) QC Lab to have at least four kits for testing collected samples, and the Faculty of Pharmacy at Kabul University to have two kits for training purposes.

The finalized proposal for piloting in these two sites was approved by the NMFB on August 12, 2014, and endorsed by the deputy minister for technical affairs on September 10, 2014. A key recommendation for improving medicines regulation was for the MoPH to develop a national strategy for medicines quality assurance, which includes a risk-based sampling and screening with GPHF-Minilabs for a number of medicines at selected points in the supply chain system.[5] This includes testing at the major distribution and post-market surveillance points, national laboratory, and university.

Several reports concern for existence of substandard, falsified, adulterated, and diverted medicines in Afghanistan. Afghanistan has weak capacity for medicines regulation and control for both public and

[1] SEAM Conference 2001. Roundtable #6: *Ensuring Medicine Product Quality*. www.msh.org/seam/conference2001/roundtable6.html
[2] Paterson, A. and A. Karimi. 2005. *Understanding Markets in Afghanistan: A Survey of the Market for Pharmaceuticals.* Kabul: Afghanistan Research and Evaluation Unit.
[3] Jiyeun (Tori) Kim. *Implementing Minilab for Screening of Pharmaceuticals.* June 2011.
[4] http://www.gphf.org/web/en/minilab/index.htm
[5] Yusuf et al. *Afghanistan Medicines Sampling and Testing – A Quantitative Survey.* April 2011.

private sectors. Several surveys conducted by the MoPH and the SPS project[6,7] showed a lack of structures, procedures, and policies to regulate the pharmaceutical sector to properly assure quality. Other studies identified the weakness in medicine inspection in Afghanistan and recommended strengthening supply chain oversight through appropriate legal provisions including enforcing medicine inspection.[8,9] A quantitative survey conducted by the MoPH and SPS in 2011 showed that 9 percent of a sample of medicines in the public and private sectors of Afghanistan failed to comply with established international pharmacopeia standards. The survey noted that this result could be an underestimation.

With the commitment of improving quality of medicines, the MoPH decided to strengthen the NMFB, subsequently establishing the Medicine Committee and the QASC, which will provide an advisory, coordination, and oversight role on the medicines quality assurance system in Afghanistan. In addition, the MoPH and its General Directorate of Pharmaceutical Affairs (GDPA) adopted the GPHF-Minilab pilot proposal for inspection at pharmaceutical establishments (e.g., wholesalers and retailers). Therefore, there is a need to build the QASC's capacity in their strategic and technical oversight role for medicine quality assurance, as well as the GDPA and FDQCD's capacity in inspection through the piloting of the GPHF-Minilab.

2. OBJECTIVES AND SCOPE OF THE ASSIGNMENT

2.1. The Purpose of the Assignment

The purpose of this activity was to support the MoPH with the development, adoption, and implementation of a plan for piloting GPHF-Minilab for quality assurance in the pharmaceutical sector, and to build the capacity of the QASC in managing and overseeing the nation's medicines quality assurance system. The SPS team and the GDPA identified the need for an international consultant to lead these activities and work in collaboration with the SPS team, MoPH, and other key stakeholders.

2.2. Objectives

- To assist the GDPA and FDQCD to conduct a pilot of GPHF-Minilab testing as an integral component of the national quality assurance program
- Conduct a GPHF-Minilab pilot project in selected sites of Afghanistan for a specific period of time. So as to:
  - Assess the benefits of the GPHF-Minilab
  - Assess the ability of the mechanism to operate in the prevailing sites of the country

2.3. Assignment Tasks

The terms of reference lists the consultant's activities as follows—

- Build capacity of QASC, MoPH, and other key stakeholders in pharmaceutical quality assurance
- Review the GPHF-Minilab piloting proposal
- Develop the GPHF-Minilab piloting plan
- Prepare guidelines, standard operating procedures (SOPs), tools, and training/orientation materials required for GPHF-Minilab piloting
- Facilitate the GPHF-Minilab piloting training/orientation [in-country support]
- Provide follow-up support according to the pilot plan (including responding to any queries from the team, assisting with data analysis, and reporting) [remote and in-country support]
- Provide technical oversight for GPHF-Minilab piloting, in coordination with other quality assurance activities or updates
- Prepare a technical report of GPHF-Minilab pilot implementation and training course report

[6] *Afghanistan Medicine Quality Assurance Assessment – A Qualitative Survey.* April 2011.
[7] Assessment report on regulatory framework and structure for medicines and food in Afghanistan Nov 2010
[8] Jonathan Harper and Gunnar Strote, "Afghanistan pharmaceutical sector development: problems and prospects." *Southern Med Review* (2011) 4;1:29-39.
[9] Results of the Capacity Building Project "Technical Assistance to General Directorate of Pharmaceutical Affairs of Ministry of Public Health – Afghanistan"

3. METHODOLOGY

3.1. Preparation of the Pilot Documents

The study of the GPHF-Minilab was designed to achieve a fair representation of both public and private major institutions in the supply chain of pharmaceutical products at different levels. Secure urban and rural areas of the country were visited.

The extensive review of documents in consultation with field teams enabled the consultant to gain insight into Afghanistan's specific situation and the total inventory of the documents to be prepared. The list of documents consulted is shown in table 1.

Table 1. List of documents consulted

S/No	Document Title
1	Mini-lab piloting proposal
2	*Afghanistan Medicine Quality Assurance Assessment – A Qualitative Survey*. April 2011
3	*Assessment Report on Regulatory Framework and Structure for Medicines and Food in Afghanistan.* Nov. 2010
4	Jonathan Harper and Gunnar Strote. 2011. Afghanistan pharmaceutical sector development: problems and prospects. *Southern Med Review* (2011) 4;1:29-39
5	Results of the Capacity Building Project "Technical Assistance to General Directorate of Pharmaceutical Affairs of Ministry of Public Health – Afghanistan"
6	Medicines Registration Guideline, 2014
7	Terms of Reference National Medicines and Food Board, 22 October 2011
8	National Quality Assurance Policy for Pharmaceutical Products: August 2014

3.2. Pilot GPHF-Minilab Implementation

3.2.1. Study Provinces

The selection of sites for the GPHF-Minilab pilot was based on the ultimate benefits to be derived from the use of this intervention at strategic points in the pharmaceutical supply chain system across the country. It has also drawn largely on elements from the previous *Afghanistan Medicines Sampling and Testing – A Quantitative Survey*[10] that identified provinces that operate as commercial hub of goods and services (including pharmaceuticals) and that are likely to have products failing the quality specifications. Six provinces were included in the pilot phase (table 2).[11]

The GDPA, FDQCD, HLIED, Faculty of Pharmacy, and SPS project jointly conducted the medicines sampling. The QASC, mandated by the MoPH, led the planning and implementation process with technical assistance from SPS and a team of external consultants. Approval for this survey was secured from the MoPH.

Pharmacists, university lecturers, and pharmacy assistants who had in-depth knowledge in medicines supply in Afghanistan collected most of the samples. To ensure understanding, they were trained on the theoretical and practical aspects of the survey and sampling methodology. This was especially necessary as the documents and data collection tool were translated into Dari. The completed data collection tools were then translated into English for entry and analysis. The data were reviewed for consistency and accuracy by a team of consultants. All the necessary queries and questions were compiled and sent back to the QASC, which provided answers and clarifications.

[10]Inua Yusuf, D. Lee, Zakeria Fatehzada., Wahidullah Karwar., M. Morris, M. Zafar Omari, Aisha Noorzaee and T. Layloff. April 2011. *Afghanistan Medicines Sampling and Testing – A Quantitative Survey*. Submitted to the USAID by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

[11] Afghanistan Information Management System, http://www.aims.org.af /ssroots.aspx?seckeyt=400

Table 2. Distribution of sample collected, per province surveyed, by facility type

		Type of Facility (#)		Total
		Private	Public	
Province	Balkh	16	16	32
	Herat	16	16	32
	Kabul	18	14	32
	Kandahar	15	17	32
	Kunduz	16	15	31
	Nangarhar	15	17	32
Total:		98	93	191

Note: *Facility types surveyed include public regional hospitals, basic health centers, comprehensive health centers, district hospitals, importers, and national hospitals, as well as private hospitals and clinics, retail pharmacies, and wholesale pharmacies.*

3.2.2. Sampling Process

This analysis is based on collected samples of medicines for testing by GPHF-Minilab. The medicines sampling and testing survey did not intend to establish the prevalence of substandard and/or counterfeit medicines, nor was it intended to quantify the extent of the problem. It was performed to determine whether GPHF-Minilab would be suitable if there were substandard or counterfeit essential medicines in health facilities in the public or donor-supported sector and in the private-for-profit sector. The sampling plan and protocols were approved by QASC before sampling was conducted.

The survey did not track product origin, storage condition, or in many instances credible mechanisms of establishing the real sources of the medicines collected. The survey only collected the samples from the various health facilities and recorded available information on the packages. Background information on the samples was collected strictly and exclusively from the respective packages of the samples.

Medicine products that were collected are presented in Annex 1. All 16 products were collected from both public and private facilities. Two categories of samples were considered—

- Category 1: A minimum of 50 administration units for tablets and capsules from the same batch, depending on the presentation. Sampling ensured that samples were collected in original packages (primary/secondary).
- Category 2: 10 units for injectable (e.g., vials, ampoules)

All samples were collected based on the Essential Medicines List (EML) of Afghanistan in accordance. Each sample collection team collected all targeted drug samples as per list in Annex 1, and identified each sample with a unique code number. Each team visited the facilities in the designated provinces according to the sampling plan. In a facility, every different batch of the target medicine was considered as a sample and was sampled. If more than one carton of the same batch was available in a facility, the sample was to be picked from one carton selected randomly. Sampling within a carton was also random between top, middle, and lower positions to avoid taking always from the top position or top carton. For each sample collected, the sampling person filled and signed the Sample Collection Form (Annex 2), and put the samples and forms into a dedicated zipper bags.

The samples collected were sent to SPS Country Office ensuring the storage requirements of the medicines that were collected and sealed under quarantine of QASC supervision. Following the GPHF-Minilab training, the sample boxes were opened, coded to avoid analyst bias, and randomized either to the FDQCD in the MoPH or the quality control lab at the Faculty of Pharmacy. Table 3 is a cross-tabulation of distribution of sampled facility types versus selected province.

Table 3. A Cross-tabulation of distribution of sampled medicine by facility types in the selected provinces

Items		Type of facility		Total
		Private	Public	
Generic name	Acetyl salicylic acid, 500 mg tablet	6	6	12
	Amoxicillin, 500 mg capsule	6	6	12
	Chloramphenicol, 250 mg capsule	7	5	12
	Chloroquine, 150 mg tablet	7	5	12
	Ciprofloxacin, 500 mg tablet	6	6	12
	Erythromycin, 500 mg or 250 mg tablet	6	5	11
	Gentamycin, 40 mg or 80 mg injection	6	6	12
	Ibuprofen, 200 mg or 400 mg tablet	6	6	12
	Mebendazole, 100 mg	6	6	12
	Methyl dopa, 250 mg tablet	6	6	12
	Metronidazole, 200 mg or 400 mg tablet	6	6	12
	Paracetamol, 500 mg tablet	6	6	12
	Prednisolone, 5 mg tablet	6	6	12
	Rifampicin, 300 mg tablet	6	6	12
	Salbutamol, 2 mg or 4 mg tablet	6	6	12
	Sulfamethoxazole + trimethoprim, 400 mg + 80 mg tablet	6	6	12
	Total:	**98**	**93**	**191**

3.2.3. Sample Collection Techniques

Sample takers were identified from members drawn from different authorities within MoPH, and received training on the sampling process. The training also included familiarization with the study tools such as GPHF-Minilab Survey of Protocol for the Quality of Selected Essential Medicines in Pilot Provinces of Afghanistan, GPHF-Minilab Test Kit Handbook, and Sampling Plan in Private and Public Sector. Sample takers were divided into six teams under the lead QASC (see Annex 3: Sample Collection Teams).

3.2.4. Additional Precautions for Sample Collection

For each sample collected, the sample takers filled and signed the sample collection form (Annex 2) and inserted the samples and form into a dedicated envelope.

In order to avoid confusion, each sample was identified by a unique code number (as indicated below) consisting of the name of the province, type of product, sampling category, sampling date, and a sequential number of the sample.

- Province name: (1) for Kabul, (2) for Nangarhar, (3) for Kunduz, (4) for Balkh, (5) for Herat, and (6) for Kandahar
- Type of product: (AB) for antibiotics, (AM) for antimalarial, (AI) for anti-inflammatory/analgesics, (ARV) for antiretroviral, (AT) for anti-tuberculosis, (AH) for anthelminthic, (AA) for antiemetic, and (OT) for others
- Sampling category: (1) for public sector and (2) for private sector
- Sampling date: DD-MM-YY
- Sample sequential number: from 01 to 191

When it is necessary to collect more than one original package in order to obtain the required number of units, all original packages were marked with the appropriate sample code number.

Sample envelopes were labeled with sample code number, international nonproprietary name (INN), and trade name of each product.

3.2.5. Information Collected

The following product details were indicated for each sample collected. The details are important not only to ensure accurate analyses but also to help differentiate one sample from another—

- Sample code number
- Product name (brand/trade name, generic name)
- Name of active ingredient or ingredients
- Dosage form
- Strength per administration unit

Table 4. Cross-tabulation of dosage forms collected as a function of facility types

		Type of facility		Total
		Private	Public	
Dosage form types	Capsule	16	11	27
	Injectable	6	6	12
	Tablet	76	76	152
Total:		**98**	**93**	**191**

3.2.6. Handling and Storing of Samples

Samples collected were packed in zipper bags, transported, and stored in such a way as to prevent any deterioration, contamination, or adulteration. For example, samples collected were immediately placed securely in moisture protective bags, stored away from temperature extremes, and transported in accordance with storage instructions for the respective product.

The flowchart in Annex 8 outlines the steps followed after sample collection.

3.2.7. Sample Transportation and Documentation for Quality Control Laboratory Testing

Adequate care and measures were taken to ensure that samples reached the site where the tests were performed (both basic testing using the GPHF-Minilab [Tier 1] and QC verification test lab [Tier 2]) without any physical or chemical damage. For example, boxes were sealed and labeled before leaving the sample site to ensure sample integrity.

3.2.8. Sample Analysis

Tier 1

The GPHF-Minilab screen was performed at two locations: the FDQCD and the Faculty of Pharmacy at Kabul University. Each sample collected was processed as per schematic flow in Annex 8 using GPHF-Minilab physical inspection, disintegration, thin-layer chromatography (TLC) assay and identification, and following specific SOPs.

Samples that failed GPHF-Minilab testing were classified as failed at basic quality testing. Samples were sent to Tier 2 laboratories for testing on the basis of the following criteria—

- All of the samples that failed at basic quality testing and doubtful samples (n=10)
- Four percent of all samples (n=8) that passed GPHF-Minilab testing

Tier 2

As enumerated above, 18 samples were selected for Tier 2 confirmatory testing at the designated QC Lab (10 that failed Tier 1 testing and eight that passed). Tier 2 testing was based on the fourth edition of International Pharmacopoeia (2006), or the latest editions of British Pharmacopoeia or United States Pharmacopoeia 30–National Formulary 25.

3.2.9. Data Management

A Microsoft Access database was created where data sets from all field forms were considered (see Annex 2: Sample Collection Form, Annex 4: Physical Inspection Results Form and Annex 5 GPHF-Minilab Screening Testing Form). A Statistical Software for Social Scientist Version 17 database was created whereby all data from field and laboratory testing were entered, cleaned, and analysed to generate results tables. Data quality was verified by checking randomly selected original forms against the corresponding database entry.

4. RESULTS AND DISCUSSION

4.1. Preparation of the Pilot Documents

The assignment was undertaken remotely with extensive consultation with field teams and MoPH through the QASC. The following documents were developed and used for training and support throughout the implementation of the GPHF-Minilab pilot.

The team prepared the following materials—

- Lecture 1. Risk-Based Drug Quality Concept
- Lecture 2. Introduction to GPHF-Minilab Kit
- Lecture 3. General Introduction to Chromatography

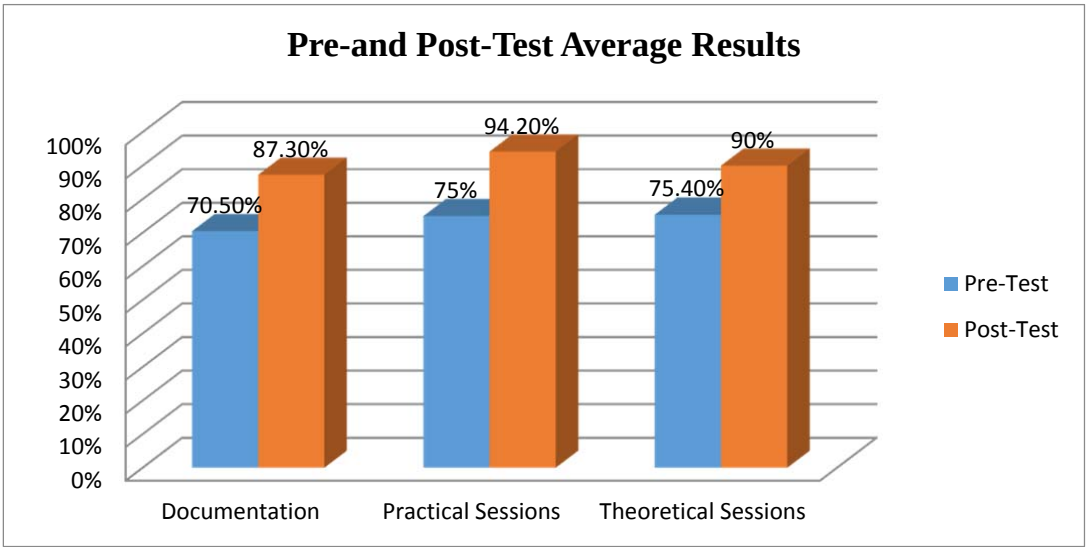
- Lecture 4. TLC Applications in GPHF-Minilab for Quality Control of Drugs
- Lecture 5. Sampling
- GPHF-Minilab Test Kit Handbook: A Systematic Guide, including SOPs for sampling, inspection, testing, sampling forms, test forms, and GPHF-Minilab supply inventory management instructions
- GPHF-Minilab Survey Protocol, providing detailed instructions on the target medicine and selection criteria, target provinces/districts, facilities by types, sampling techniques, number of samples, information to be collected, sample handling, and sample collection forms
- List of training supplies needed to establish 10 training stations, so that all trainees could access and practice with the basic apparatus typical for GPHF-Minilab testing.

4.2. GPHF-Minilab Training

A total of 10 training stations were established at the Faculty of Pharmacy at Kabul University. A competency-based training package was developed and the SPS project successfully conducted the training from March 23 to April 1, 2015. A total of 25 key staff participated: four representing the GDPA, four from the FDQCD, two from the Health Legislation Implementation Ensuring Directorate (HLIED), four from the Faculty of Pharmacy of Kabul University, six from the QASC, two from the Monitoring and Evaluation (M&E) Directorate of MoPH, and three from the SPS project. The training was conducted in a very good environment and with active participation of participants and facilitators. All the participants were heavily engaged, and the course schedule and plan were fully implemented.

Pre- and post-test evaluations of the participants were performed, and results were analyzed and compared. The pre-test average scores in each evaluative domain (documentation, theoretical sessions, and practical sessions) were 70.5 percent, 75 percent, and 75.4 percent. These increased in post-test to 87.3 percent, 94.2 percent, and 90 percent (figure 1). The results showed that, on average, scores increased more than 15 percentage points for documentation, almost 20 percentage points for theoretical sessions, and almost 15 percentage points for practical sessions. Participant level of satisfaction was also assessed in terms of the relevance of information to their needs, and the quality of each instructor's presentation and subject matter knowledge, of training facilities, and of the workshop overall. On average, participant satisfaction was 83.6 percent.

Figure 1. Improvement in participant's pre- and post-workshop evaluation of the three evaluative domains



4.3. Distribution of Samples

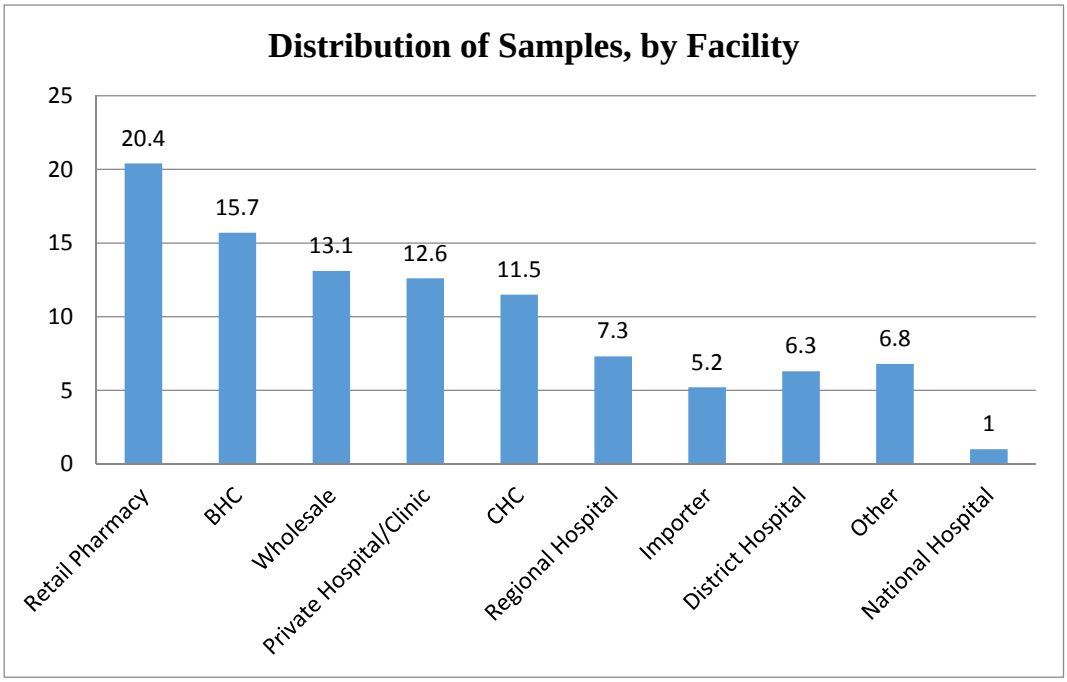
Out of 191 samples, 98 (51.3 percent) were collected from private facilities while 93 (48.6 percent) were public facilities. The majority of dosage forms studied were tablets (152, or 79.6 percent), followed by capsules (27, or 14.1 percent) and injectable solutions (12, or 6.3 percent) (table 5).

Table 5. Distribution of the of the dosage form description, by facility type

			Type of facility		Total
			Private	Public	
Dosage form type	Capsule	*Count*	16	11	27
		% of total	16.33	11.83	14.1
	Injectable	*Count*	6	6	12
		% of total	6.12	6.45	6.3
	Tablet	*Count*	76	76	152
		% of total	77.55	81.72	79.6
Total:		*Count*	98	93	191
		% of total	51.31	48.69	100.0

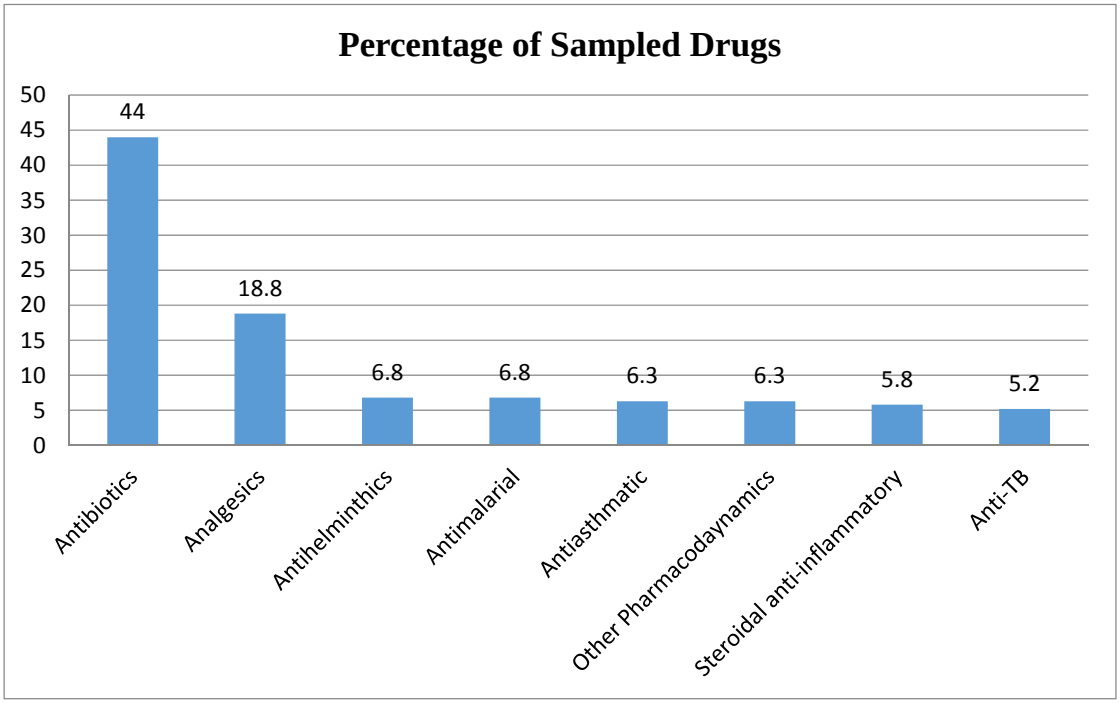
The majority of samples came from private pharmacy retail outlets (20.4 percent, n=39), basic health centers (15.7 percent, n= 30), private pharmacy wholesalers (13.1 percent, n=25), private hospital or clinics (12.6 percent, n=24), comprehensive health centers (11.5 percent, n=22), and regional hospitals (7.3 percent, n=14). See figure 2 for additional detail.

Figure 2. Distribution of samples, as a function of facilities sampled



Although initially it was planned to also include some informal medicine outlets, this could not be done because of time and security limitations. It was also determined to be unnecessary because the study's purpose was to pilot the process of implementing a tiered approach in medicine testing and learn the challenges of implementing such a process, rather than to generate an indicative report on the quality of medicine in Afghanistan. About half of the total medicines collected were antibiotics (44 percent), followed by analgesics (18.8 percent); the rest were less than 10 percent each (figure 3).

Figure 3. Samples collected by their pharmacological classification groups



4.4. Tier 1 Test Results

4.4.1. Physical Inspection

Visual inspections did not reveal any serious deficiencies in medicine packaging: all correctly described the dosage, type of drug, expiry date, manufacture date, etc. See figure 4 for a presentation of the physical inspection outcomes by country of product origin.

Visual inspections of the tablets/capsules themselves revealed some problems: about 27 percent of tablets had breaks, cracks, splitting, capping, and/or cavitations, and about 21 percent had embedded surface spots or foreign particulate contamination (table 6). The rest were of the correct color and size, were not chipped or cracked, and exhibited no other severe deficiencies. The majority of capsules passed physical inspection, but 18.5 percent had a weak point in the body of the capsule.

Table 6. Physical inspection of the tablets

Parameters	Pass		Fail	
	Count	%	Count	%
Odor (immediately on opening the outer container)	152	100	0	0.0
Odor (after exposing the tablets according to recommended plan of exposure)	152	100	0	0.0
Uniformity of size, shape, color, and coating (visual inspection)	140	92.1	12	7.9
Tablet core fully covered	146	96.1	6	3.9
Polishing	129	84.8	23	15.2
Markings (scoring, letters, etc.)	141	92.8	11	7.2
Breaks, cracks, splitting, capping, and cavitations	111	73	41	27
Embedded surface spots, foreign particulate contamination	119	78.3	33	21.7

Table 7. Physical inspection of the capsules

Parameters	Pass		Fail	
	Count	%	Count	%
Registration status	0	0.0	0	0.0
Odor (on immediately on opening the outer container)	27	100	0	0.0
Odor (after exposing the capsules according to recommended plan of exposure)	27	100	0	0.0
Presence of empty, broken, or separated capsules	27	100	0	0.0
Pinholes in capsules	27	100	0	0.0
Stickiness between capsules	25	92.6	2	7.4
Container/bottle free of powder and/or extraneous material	25	92.6	2	7.4
Weak point in body of capsule	22	81.5	5	18.5

Figure 4: Presentation of visual inspection outcome, by country of product origin

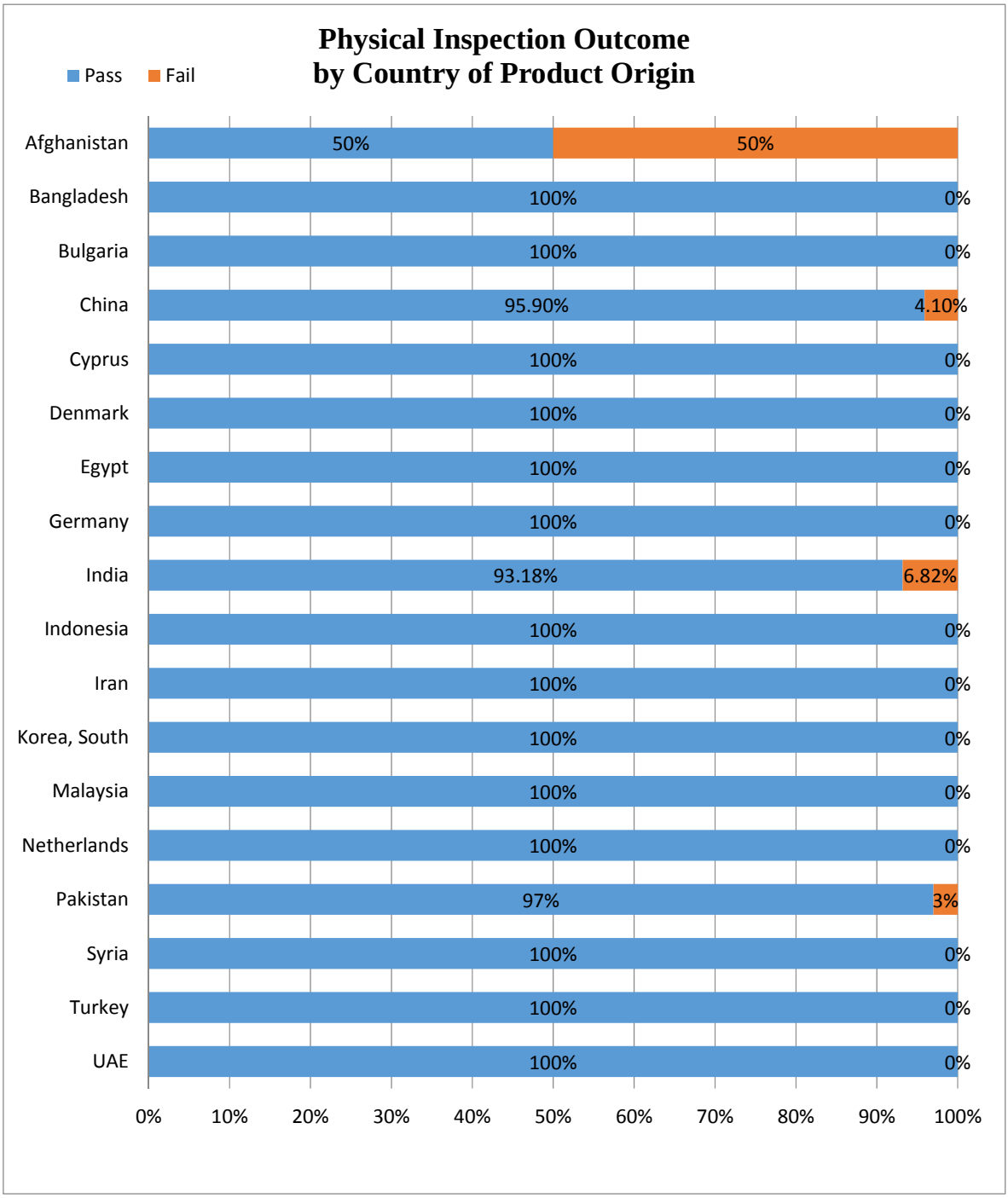


Table 8. Tabulation of the visual inspection results by the country of manufacturing[12]

			Visual inspection plus		Total
			Pass	Fail	
Country of Manufacturing	Afghanistan	*Count*	1	1	2
		% within country of manufacturing	50	50	100
	Bangladesh	*Count*	2	0	2
		% within country of manufacturing	100	0.0	100
	Bulgaria	*Count*	1	0	1
		% within country of manufacturing	100	0.0	100
	China	*Count*	23	1	24
		% within country of manufacturing	95.9	4.10	100
	Cyprus	*Count*	5	0	5
		% within country of manufacturing	100	0.0	100
	Denmark	*Count*	7	0	7
		% within country of manufacturing	100	0.0	100
	Egypt	*Count*	1	0	1
		% within country of manufacturing	100	0.0	100
	Germany	*Count*	2	0	2
		% within country of manufacturing	100	0.0	100
	India	*Count*	40	4	44
		% within country of manufacturing	93.1	6.82	100
	Indonesia	*Count*	1	0	1
		% within country of manufacturing	100	0.0	100
	Iran	*Count*	29	0	29
		% within country of manufacturing	100	0.0	100
	Korea, South	*Count*	1	0	1
		% within country of manufacturing	100	0.0	100
	Malaysia	*Count*	1	0	1
		% within country of manufacturing	100	0.0	100
	Netherlands	*Count*	2	0	2
		% within country of manufacturing	100	0.0	100
	Pakistan	*Count*	58	2	60
		% within country of manufacturing	96.6	3.33	100
	Syria	*Count*	1	0	1
		% within country of manufacturing	100	0.0	100
	Turkey	*Count*	2	0	2
		% within country of manufacturing	100	0.0	100
	United Arab Emirates	*Count*	6	0	6
		% within country of manufacturing	100	0.0	100
Total:		*Count*	183	8	191
		%	95,81	4,18	100

4.4.2. Disintegration Test

Out of 191 samples tested 179 (93.7 percent) were solid dosage forms (tablets and capsules); all passed the disintegration testing at 100 percent (table 9). The fact that all tablet and capsule samples passed the disintegration tests suggests satisfactory formulation skills within the manufacturers from which the formulations were collected.

4.4.3. Color Reaction

The color reaction was carried out on all 191 samples; two samples (1 percent) failed to react positively with respective to coloring dye. The remaining 189 samples (99 percent) reacted positively (table 9). Regardless of the pass/fail status, all samples were tested for verification of content and identification (by TLC); all samples passed the identity test.

[12] Source: Product label descriptions

Table 9. The overall summary of tests performed with outcome statement

Test performed	GPHF-Minilab Screening Tests			
	Pass		Fail	
	Count	%	Count	%
Visual inspection	183	96	8	4
Disintegration	179	100	0	0
Color reaction	189	99	2	1
Thin-layer chromatography	190	99	1	1
Overall final results	180	94.77	10*	5.23

*****One sample failed two tests (visual inspection and color reaction), thus a total of 10 samples failed Tier 1 testing.

4.4.4. Verification of Content by Semi-quantitative TLC Assay

All 191 samples of 16 assorted medicines were tested by TLC to verify content and identification, as per the procedure described in the respective protocol in the GPHF-Minilab manual. The test results revealed that 99 percent of products passed this test (table 9).

Test Turnaround Time

Analysts were asked to record the beginning and end time for every test. The results showed that the average sample analysis time was 1.5 hours per full time equivalent (FTE) analyst—a rate that is consistent with the average analysis time in other countries. The values ranged from 0.42 to 6.17 hours (table 10). This is a significant achievement, given that the Afghan analyst did not have prior experience with GPHF-Minilab testing. As analysts in Afghanistan acquire greater proficiency, the analysis time may continue to improve, making the GPHF-Minilab process even more efficient.[13]

Table 10. Average sample screening time, per FTE

	N	Minimum	Maximum	Mean	Std. deviation
Sample analysis time (hours)	191	0,42	6.17	1.5	0,60715

Product Remaining Shelf Life

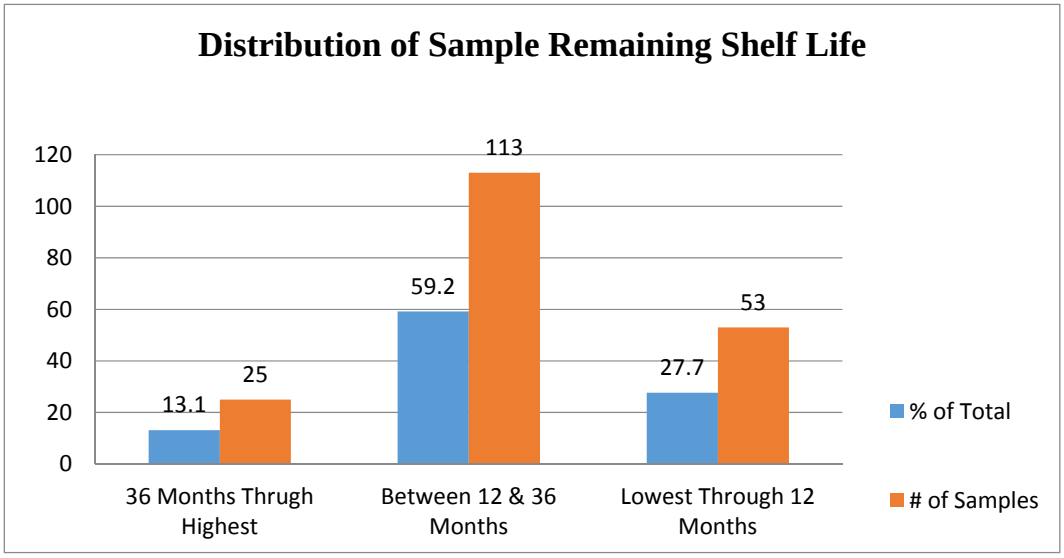
From the supply chain management perspective, results about the remaining shelf life of products are very encouraging. On average, the remaining shelf life was 19.5 months per product, with values ranging from 0.07 to 54 months (table 11 and figure 5). More than 70 percent of the products in the market had a remaining shelf life of more than one year; intensive efforts to improve medicine supply chain management in Afghanistan might have contributed to this positive finding.

Table 11. Average remaining shelf life of sampled product

	N	Minimum	Maximum	Mean	Std. deviation
What is the remaining shelf life at the testing date (months)?	191	0,07	54.44	19.5	12.7

[13] TANZANIA: Product Quality Assurance Program, http://projects.msh.org/seam/reports/SEAM_TANZANIA_Quality_Assurance.pdf (Accessed July 2, 2015.)

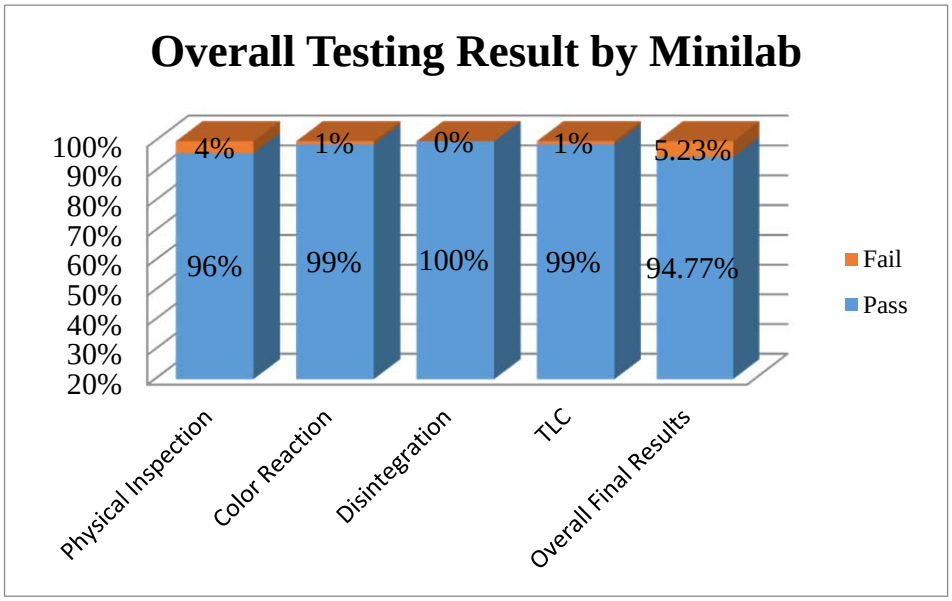
Figure 5. Distribution of the remaining shelf life of sampled product, by different age groups



4.5. The Overall Evaluation of Sample Compliance with Basic Screening Test

Overall evaluation of sample compliance with basic testing is summarized in figure 6 and detailed in table 12. This figure pooled together all assessed parameters from visual inspection, disintegration testing, and verification of content and identification by TLC. The study has revealed 4 percent, 1 percent, and 1 percent failing rates for visual inspection, color reaction, and TLC test respectively, however the samples that failed visual inspection and color reaction test nearly all passed the TLC (99 percent). Thus 94, 77 percent of all products tested met the quality standards. Afghanistan National Pharmaceutical Quality Assurance Policy[14] states that products sampled from the market place failing TLC tests, are be seized and destroyed by the National Medicine Regulatory Authority (NMRA), and cost of the destruction charged to the product owner.

Figure 6: The overall testing summary for the basic testing with GPHF-Minilab



[14] Islamic Republic of Afghanistan Ministry of Public Health General Directorate of Pharmaceutical Affairs, National Medicines Quality Assurance Policy, 2015

Table 12. Detailed outcomes of the various testing methods

Item name	# tested	Visual inspection		Disintegration inspection		Color reaction		TLC		Final result	
		% Pass (N = 183)	% Fail (N = 8)	% Pass (N = 191)	% Fail (N = 0)	% Pass (N = 189)	% Fail (N = 2)	% Pass (N = 190)	% Fail (N = 1)	% Pass (N = 182)	% Fail (N = 9)
Salbutamol, 4 mg	12	83% n = 10	17% n = 2	100% n = 12	0% n = 0	83% n = 10	17% n = 2	100% n = 0	0% n = 0	75% n = 9	25% n = 3
Chloroquine, 150 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	92% n = 11	8% n = 1	92% n = 11	8% n = 1
Paracetamol, 500 mg	12	83% n = 10	17% n = 2	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	83% n = 10	17% n = 2
Prednisolone, 5 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Rifampicin, 300 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Mebendazol, 100 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Metronidazole, 400 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Co-trimoxazole, 480 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Ciprofloxacin, 500 mg	12	92% n = 11	8% n = 1	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	92% n = 11	8% n = 1
Erythromycin, 500 mg	11	100% n = 11	0% n = 0	100% n = 11	0% n = 0	100% n = 11	0% n = 0	100% n = 11	0% n = 0	100% n = 11	0% n = 0
Gentamicin, 40 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Methyl dopa, 250 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Ibuprofen 400 mg	12	92% n = 11	8% n = 1	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	92% n = 11	8% n = 1
Amoxicillin, 500 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Acetyl salicylic acid, 500 mg	12	83% n = 10	17% n = 2	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	83% n = 10	17% n = 2
Chloramphenicol, 250 mg	12	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0	100% n = 12	0% n = 0
Grand Total (%)	**191**	**96%**	**4%**	**100%**	**0%**	**99%**	**1%**	**99%**	**1%**	**94.77%**	**5.23%**

4.6. Tier 2 Test Results

A total of 18 samples were subjected to Tier 2 pharmacopeia confirmatory tests. The figure included 10 samples that failed Tier 1 testing (7 failed physical inspection, 1 failed color reaction, 1 failed both physical and color reaction, and 1 failed TLC) and 8 that passed all Tier 1 testing.

Eight of the ten samples (80 percent) that failed Tier 1 continued to fail in Tier 2 testing, confirming those Tier 1 results. And 10 of the 18 total samples (55.5 percent) tested in Tier 2 passed Tier 2 tests (8 passed samples in Tier 1 plus two failed samples in Tier 1) (table 13).

In conclusion, 89 percent of Tier 1 and Tier 2 tests results are matching which shows good and acceptable performance of the GPHF-Minilab compare to pharmacopeia confirmatory lab tests.

Table .13Tier 2 pharmacopeia confirmatory tests

	Tier 2 pharmacopeia confirmatory tests			
	Pass		**Fail**	
	Count	**%**	**Count**	**%**
Pharmacopeia testing (N=18)	10	55.5	8	44.5

Table 14. Overall results: Tier 1 and Tier 2

		Tier 2		**Total**
		Pass: Count (%)	**Fail: Count (%)**	
Tier 1	Pass: Count (%)	2 (11.1%)	8 (44.4%)	10
	Fail: Count (%)	8 (44.4%)	0 (0%)	8
	Total:	10	8	18

5. OVERALL EVALUATION OF PILOT GPHF-MINILAB PROGRAM

A total of 191 samples were subjected to a risk-based, phased approach to quality testing: 183 samples (95.8 percent) passed overall and eight (4.2 percent) failed overall (table 14). Tier 1 and Tier 2 testing found similar percentages of failing medicines in their samples (5.23 percent and 4.2 percent, respectively, as presented in tables 9 and 13). This finding confirms the overall accuracy of GPHF-Minilab testing, even when used in a challenging environment such as Afghanistan. This accuracy, combined with the low cost and rapid testing time, confirm that the GPHF-Minilab would be a feasible and valuable tool for medicine quality assurance in Afghanistan.

Table 15. The overall performance of the pilot GPHF-Minilab project

	Overall quality testing (Tier 1 and Tier 2)			
	Pass		**Fail**	
	Count	**%**	**Count**	**%**
Total samples (N=191)	183	95.8	8	4.2

6. CONCLUDING REMARKS

A competent team of experts was created at MoPH and Kabul University, and provided with training materials in order to ensure the future sustainability of the training with reduced dependence on foreign international technical advisors (ITAs). Various documents were developed to guide the implementation of the pilot GPHF-Minilab project. This study has demonstrated that a phased GPHF-Minilab implementation is a viable, risk-based quality assurance option in Afghanistan. Screening tests such as the GPHF-Minilab are relatively inexpensive, rapid, and provide a simple assessment of medicine quality and therefore have an important role to play in the monitoring of medicine quality in resource-poor and rural settings such as in Afghanistan. The short screening time per sample per FTE indicates that the technology has untapped potential for deployment as a preliminary screening tool to reduce the number of samples sent to the central lab for full monograph testing.

7. OVERALL RECOMMENDATIONS

Following a successful pilot implementation of the GPHF-Minilab in a scenario that mimics a post-marketing surveillance and testing of the pharmaceuticals products circulating in Afghanistan, this study recommends the following—

- The National Regulatory Authority, in order to strengthen quality assurance in the pre and post regulatory activities in regard to pharmaceutical product entering to market, can make use of this technology according to the tiered approach prescribed in the recently approved Afghanistan National Pharmaceutical Quality Assurance Policy.
- Use of GPHF-Minilab kits would also benefit other players including nongovernmental organizations (NGOs), warehouses, hospitals and other health facilities to test their related pharmaceutical products. This kind of putting the regulatory activities in use is distinct and can only be administered for self-assessment purposes.
- GPHF-Minilab can analyse a specified number of medicines in a short time with low-cost infrastructure; it offers substantial time savings and can support the QC lab regarding medicine quality in Afghanistan.
- A study tour is recommended to countries where the GPHF-Minilab has been utilized, prior to its actual implementation in Afghanistan.
- Dissemination of study findings to a wider stakeholder audience.

8. LIMITATIONS

The sample collection locations were limited to sites that were secure for the sample takers during the sampling period. It was not possible to assess the registration status of the products, as registration numbers are not yet available on all product labels. (This requirement is in the process of being implemented.) Other indicators—such as monetary value of shipments inspected, monetary value of shipments tested, monetary value of shipments found to be substandard/counterfeit, and ratio of substandard/counterfeits detected to expenditure on testing—could not be reported because of the final study design (which excluded the port of entry).

ANNEXES

Annex 1: List of Medicines for GPHF-Minilab Test Pilot Study

S/No	Classification	Selected Items
1	Antibiotics	• Ampicillin 500 mg Capsule, • Co-Trimoxazol 480 mg Tablet, • Ciprofloxacin 500 mg Tablet, • Erythromycin 400 mg or 200 mg Tablet, • Gentamycin 40 mg or 80 mg Injection, • Chloramphenicol 250 mg Capsule, • Metronidazole 200 mg or 400 mg Tablet,
2	Antimalarial	• Chloroquine 150 mg Tablet
3	Anti-TB	• Rifampicin 300 mg or Rifampicin + INH 150 mg + 300 mg Tablet
4	Analgesics	• Ibuprofen 200 mg or 400 mg Tablet, • Paracetamol 500 mg Tablet, • Acetyl Salicylic Acid 500 mg Tablet
5	Steroidal anti-inflammatory	• Prednisolone 5 mg Tablet
6	Anthelminthic	• Mebendazole 100 mg
7	Antiasthmatic	• Salbutamol 2 mg or 4 mg Tablet
8	Other pharmacodynamics	• Methyldopa 250 mg Tablet

Annex 2: Sample Collection Form

Ministry of Public Health
National Medicines and Food Board
Quality Assurance Subcommittee
Sample Collection Form

1. Province:
1) Kabul 2) Nangarhar 3) Kundoz 4) Balkh 5) Herat 6) Kandahar

2. District:_____

3. Name of Site: _____

4. Type of Site *(Public Sector)***:**
1) National Hospital 2) Regional Hospital 3) District Hospital
4) Comprehensive Health Centre 5) Basic Health Centre 6) Others

5. Type Site *(Private Sector)***:**
1) Importer 2) Wholesaler 3) Retailer 4) Private Hospital 5) Other

6. Donor:
1) USAID 2) WB 3) EC 4) MoPH 5) Private 6) Others

7. Generic Name of Sample:_____

8. Commercial Name of Product:_____

9. Classification:
1) Antibiotics 2) Antimalarial 3) Anti TB 4) Analgesics

5) Steroidal anti-inflammatory 6) Anthelminthic 7) Antiasthmatic 8) others

10. Dosage Form:
1) Tablet 2) Capsule 3) Suspension 4) Injection

11. Strength per Unit Dose *(e.g. mg/tablet)***:** _____

12. Type and Packaging:
1) Taken from Original package 2) Taken from Bulk Container

13. Quantity Collected/per sample, with Specification of the Package Size: _____

14. Batch Number:_____

15. Manufacturing Date:_____

16. Expiry Date:_____

17. Name of Manufacturer:_____

18. Country of Manufacturer:_____

19. Regulatory Status of the Product in the country *(on the basis of GDPA records)***:**

1) Registered 2) Non-registered
If registered, marketing authorization holder and number: _____

20. Any other comment:_____

Sample Collector:
Name:
Date:
Signature:

Annex 3: Sample Collection Team Members and analysts:

S/No	Name	Organization
1	Jawed Pardisi	ANSA
2	Pro. Muhammad Amman Bahaduri	Faculty of Pharmacy KU
3	Abdul Razaq Ghiasi	Faculty of Pharmacy KU
4	Yar Muhammad Sultani	Faculty of Pharmacy KU
5	Muhammad Ibrahim	HLIED
6	Abdul Rafi	HLIED
7	Muhammad Yousouf	HLIED
8	Abdul Raqaz	HLIED
9	Friba Samad	Quality Control Lab
10	Spozhmai Norziae	Quality Control Lab
11	Sultana	Quality Control
12	Nahid Amadi	Pharmacist
13	Abdul Jamil Skandari	Quality Control Lab
14	Abdul Satar Ahmadi	GDPA
15	Muhammad Nasir Lutfi	GPDA
16	Nasir Ahmad	GDPA
17	Ahmad Farid Sarwary	Regulation Legal Office SPS
18	Beheshta Sadat	Regulation Legal Officer SPS
19	Dr. Zabiullah Ghawsi	SPS
20	Muhammad Muqim Mayar	SPS

Annex 4: Physical Inspection Results Form

Ministry of Public Health
National Medicines and Food Board
Quality Assurance Subcommittee
Physical Inspection Results Form

1. General Information

Site Name	

2. Product Information

Product Name:		
Batch Number:		
Manufacture Date:		
Expiry Date:		
Manufacturer:		
Country of Manufacturer:		
Product Form/Category (select one)		Tablets (go to Section 3A)
		Capsules (go to Section 3B)
		Liquids: solutions and syrups (go to Section 3C)
		Liquids: suspensions (go to Section 3D)
		Parenterals: solutions and suspensions (go to Section 3E)

3. Test Results and Observations

A) Tablets

S/NO	Parameter	Specifications	Status	
			Pass	**Fail**
1	Registration status	Registration Number should be clearly printed on the product		
2	Odor (immediately on opening the outer container)	No odor, except for flavored tablets and those with active ingredients normally having characteristic odor		
3	Odor (after exposing the tablets according to recommended plan of exposure)	No odor, except for flavored tablets and those with active ingredients normally having characteristic odor		
4	Uniformity of size, shape, color, and coating (visual inspection)	Uniform in size and shape, uniformity of color and coating		
5	Tablet core fully covered	Uniform coating with core fully covered		
6	Polishing	Uniformly polished and free of adhering fine powders		
7	Markings (scoring, letters, etc.)	Uniform and identical		
8	Breaks, cracks, splitting, capping, and cavitations	Free of breaks, cracks, splitting, capping, and cavitations		
9	Embedded surface spots, foreign particulate contamination	Free of embedded surface spots, foreign particulate contamination		
10	Other (specify)			

B) Capsules

S/NO	Parameter	Specifications	Status	
			Pass	Fail
1	Registration status	Registration Number should be clearly printed on the product		
2	Odor (on immediately on opening the outer container)	No odor, except for those with active ingredients normally having characteristic odor		
3	Odor (after exposing the capsules according to recommended plan of exposure)	No odor, except for those with active ingredients normally having characteristic odor		
4	Presence of empty, broken, or separated capsules	Free of empty capsules, no broken capsules		
5	Pinholes in capsules	Free of pinholes in capsules		
6	Stickiness between capsules	Capsules are not sticky		
7	Container/bottle free of powder and/or extraneous material	Container/bottle free of powder and/or extraneous material		
8	Weak point in body of capsule	No weak point in body of capsule		
9	Other (specify)			

C) Liquids: Solutions/Syrups

S/No	Parameter	Specifications	Status	
			Pass	Fail
1	Registration status	Registration Number should be clearly printed on the product		
2	Particulate matter	Should be entirely free from foreign particles		
3	Clarity	Should be clear and free of turbidity		
4	State of primary container	Should not show any evidence of cracks, breaks, tears, or leakage		
5	Other (specify)			

D) Suspensions

S/No	Parameter	Specifications	Status	
			Pass	Fail
1	Registration status	Registration Number should be clearly printed on the product		
2	Dispersability	Easily dispersed to obtain a homogeneous suspension upon moderate shaking for 20 seconds and remain homogeneous for 3 minutes		
3	State of primary container	Should not show any evidence of cracks, breaks, tears, and leakage		
4	Other (specify)			

E) Solutions/Suspensions

S/No	Parameter	Specifications	Status	
			Pass	Fail
1	Registration status	Registration Number should be clearly printed on the product		

2	Clarity	Should be clear and free of turbidity		
3	Dispersability	Easily dispersed to obtain a homogeneous suspension upon moderate shaking for 20 seconds and remain homogenous for at least 3 minutes		
4	Flowability (aqueous)	Aqueous injectable suspensions should flow freely without binding when the contents of vial/ampoule are aspirated through a 22-gauge, 1-inch hypodermic needle, using a hypodermic syringe with a suitable volume		
5	Flowability (non-aqueous)	Non-aqueous injectable suspensions should flow freely without binding when the contents of the vial/ampoule are aspirated through an 18-gauge, 1.5-inch hypodermic needle, using a hypodermic syringe with a suitable volume		
6	State of primary container	Should not show any evidence of cracks, breaks, tears, or leakage		
7	Other (specify)			

1. Conclusion/Decision

STATUS: The sample as visually inspected (tick as appropriate)		*Remarks (if any):*
	Pass	
	Fail	

2. Is there any other batch for physical examination? Y / N (circle one)

If yes, return to Section 2, Product Information, and fill in the remainder of the form for the new batch. If no, go to #6.

Names of Analyst:
Date:
Signature:

Prepared by:	**Checked by:**	**Approved by:**
Date:	**Date:**	**Date:**

Annex 5: GPHF-Minilab Screening Testing Form

Ministry of Public Health
National Medicines and Food Board
Quality Assurance Subcommittee
Minilab Screening Testing Form

SCREENING CERTIFICATE			
Station	MoPH-QC Lab:		Faculty of Pharmacy:
Sample Number		Date	

Source of Implementation of the Project	NMFB-Quality Assurance Subcommittee

PRODUCT Name:	
Active ingredients(s)	
Dosage form:	
Batch No.:	
Manufacturer	
Expire date:	
Strength :	
Date received:	
Date of analysis	
Start time (h/m)	
End time (h/m)	

Prepared by:		Checked by:		Approved by:	
Date:		Date:		Date:	

TEST	RESULTS	
	Pass	Fail
Visual		
Disintegration		
Color reaction		
Thin-layer chromatography (TLC)		
FINAL RESULTS (circle)	PASS	FAIL
COMMENTS		
ACTION TAKEN		

Name: Position: Date: Signature:

Annex 6: Distribution of Districts for Sample Collection

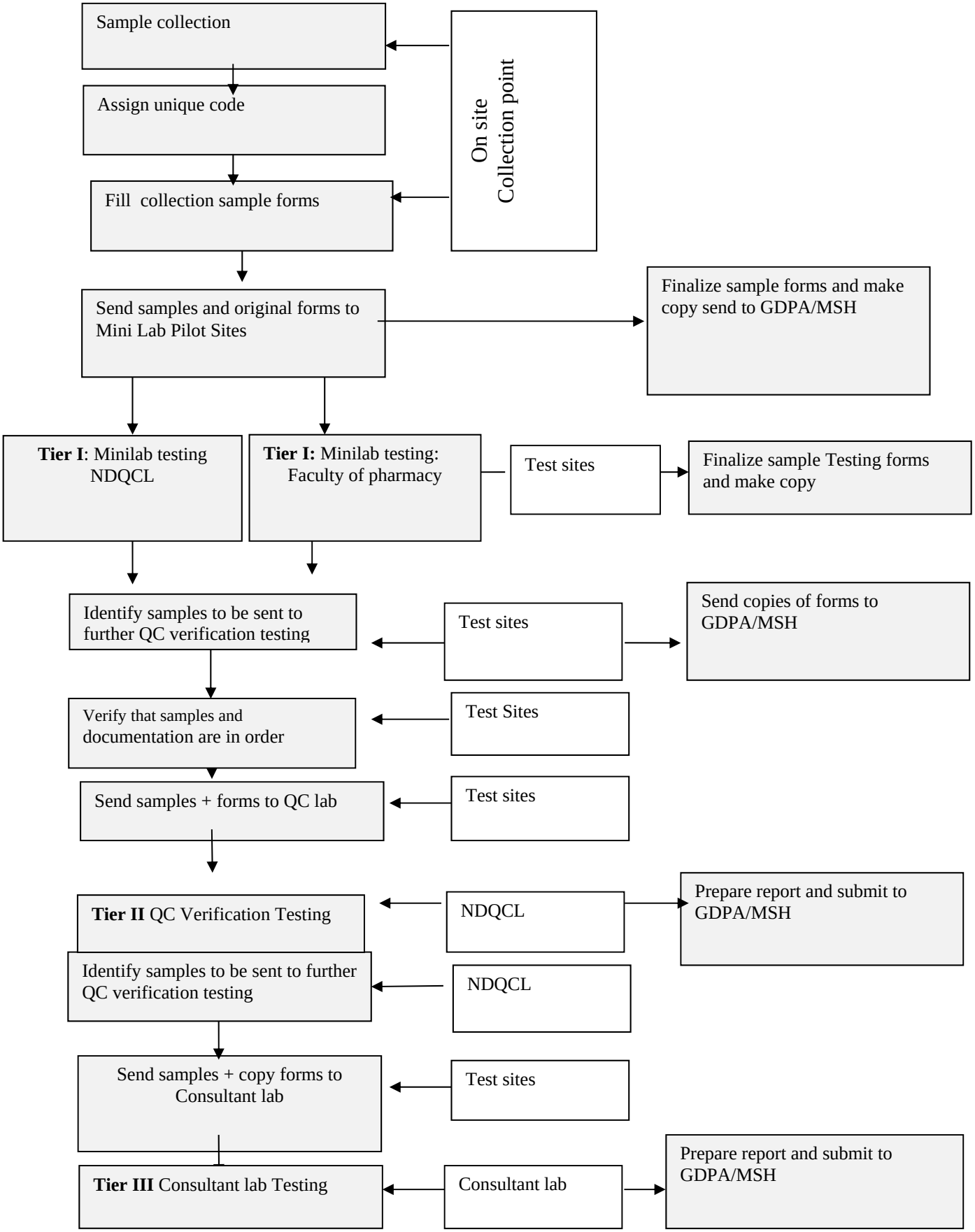
S/No	Province	Distract	Health Facility Name	Type of HF
1	Balkh	Nahie 6	Guzar Pnjshir	SC/BHC
		Wloswali Dehdadi	shirabd	BHC1
		Nahie 5	ulmarab	BHC2
		Wloswali Hairatan	Hairtan	CHC1
		Nahie 9	norkhda	CHC2
		Wloswali Balkh	Balkh	DH
		Markaz Shahar Nahie 2	B.H	RH
2	Kundoz	Markaz Kunduz	Kobahi	SC
		Wloswali Ali Abad	Arbab ramzni	BHC1
		Wloswlai Khan Abad	chartri khanabad	BHC2
		Wloswali Ali Abad	Aliabd	CHC1
		Sarak Maidan Hawae	angorbagh	CHC2
		Wloswlai Imam Saib	Amamsaib	DH
		Markaz Shahar kunduz	Kunduz RH	RH
3	Herat	Injil	Noqra	SC
		Markaz Hearat	Hawz Karbaz	BHC1
		Markaz Shahar	Jibrahil	BHC2
		Markaz Shahar	baba barq	CHC1
		Markaz Shahar	Guzargah	CHC2
		Markaz shahar	Ghrayan/ Munara	DH/ CHC3
		Herat	Herat RH	RH
4	Kandahar	Dand	chardiwar	SC/BHC3
		Shaher Kandahar	zakir sharif	BHC1
		Damman	shor andam	BHC2
		Shaher Kandahar	Mirza Muhammad	CHC1
		Kandahar	Piro Qlacha	CHC2
		Spin Boldak	Spin boldak	DH
		Shaher Kandahar	Kandahar RH	RH

S/No	Province	Distract	Health Facility Name	Type of HF
5	Nangarhar	Wloswali Kama	Zahkhil	SC
		Wloswali Khiwa	Shiga	BHC1
		Wloswlai Khiwa	Khiwa	BHC2
		Banan Ghar	Banga besod	CHC1
		Kama	Sangar Sari	CHC2
		wloswlai Kama	Kama	DH
		Markaz Shaher	Nangarh RH	RH
6	Kabul		Alawdin clic	BHC1
			agha ali shms	BHC2
			Nahey 11	CHC1
			rahman Mina clinic	CHC2
			102 Bestar	DH1
			ahmash baba H	DH2
			Inderagandui	NH1
			Rabi balkhi	NH2

Annex 7: Files Sample Validation Tool

Files Sample Collection Validation Tool							
Name of Medicines							
S/No	**Name of Site**	**Category**	**Vital Information**				
			Province	**Batch Number**	**Manufacturer**	**Expiry Date**	**Remarks**

Annex 8. Sample Flowchart



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The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to the most efficacious, safe and cost-effective medicines and appropriate use of medicines.

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