20, avenue Appia – CH-1211 Geneva 27 – Switzerland – Tel central +41 22 791 2111 – Fax central +41 22 791 3111
www.who.int

WHO PUBLIC INSPECTION REPORT (WHOPIR) Quality Control Laboratory

Part 1: General information

Name of QC Laboratory	**Mission for Essential Drugs and Supplies (MEDS)**
Physical address	MEDS Center, Mombasa Road, opposite Nation Printing Press P.O. Box 78040, Viwandani, 00507,Nairobi, Kenya
Contact personand email address.	Dr Jane Masiga, Head of Operations jmasiga@meds.or.ke Mr Stephen Kigera, QA Manager skigera@meds.or.ke
Date of inspection	22 and 23 June 2015
Type of inspection	Routine inspection
Type(s) of testing included in the inspection	Physical, chemical, and microbiological testing, including instrumentation
Summary of the testing activities performed by the QC Laboratory	

Type of analysis	*Finished products*	*Active pharmaceutical ingredients*
Physical/Chemical analysis	pH, loss on drying, water content, conductivity, refractometry, friability, disintegration, dissolution, density, uniformity of dosage unit (mass, content)	NA
Identification	HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry, TLC, chemical reaction	NA
Assay, impurities and related substances	HPLC (UV-VIS detection), GC, UV-VIS spectrophotometry,	NA

		volumetric titrations, polarimetry, Determination of related substances/impurities and degradation products **Note:** GC was not functional at the time of the inspection.		
	Microbiological tests	Microbiological tests	N/A	NA
	Stability studies	Stability studies	N/A	NA

Part 2: Summary

General information about the company and site

Mission for Essential Drugs and Supplies (hereafter MEDS) was inspected by WHO Prequalification team on the above mentioned dates.

The MEDS is a Faith Based, not-for-profit Organization established in 1986 with 3 main functions:

- Supply chain, including distribution activities: essential medicines & medical supplies that are reliable, of quality and affordable
- Capacity building & client support services: training, support to health workers, technical and professional assistance
- Pharmaceutical quality control laboratory services: assuring quality of medicines through analysis and other quality assurance mechanisms

MEDS supply chain cover over 40% of Kenya's needs and serves over 1,800 corporate clients. MEDS has a zonal distribution network which makes it easy for the facilities to get their supplies, facilities to provide physical locations for ease of delivery, facilities to give feedback on consignments within 3 days of receiving and proof of delivery provided to the NGOs for each order.

MEDS QC laboratory was established in 1997 which was necessitated by liberalisation of Kenyan economy, weak government pharmaceutical regulatory structures and costs associated with air freighting samples to laboratories in Europe.

MEDS conducts testing of medicinal products for registration of products for Pharmacy and Poisons Board (PPB), Kenya and also conducts testing for non-governmental organizations. The applicant can choose either MEDS or National Quality Control Laboratory (NQCL) for testing of their products in support of registration. It is noted that approximately 50 samples per month were tested by MEDS.

From the opening meeting presentation, MEDS had three levels wherein ground level was a reception area where orders were processed, laboratory was housed in first floor and second floor had administration, finance etc.

History of WHO and/or regulatory agency inspections

The previously inspected site was located in the Zenith Complex along Enterprise Road in Nairobi, Kenya. According to the LIF, the previous location was inspected by the following authorities:

1. World Health Organization - February 2009 leading to pre-qualification of the laboratory.

2. Joint Medical Store (JMS), Uganda - March 2011. Scope: The laboratory's Quality Management System. The laboratory was pre-qualified as a supplier of pharmaceutical analytical services to JMS.
3. QUAMED – November 2011. Scope: MEDS compliance to requirements of Good Distribution Practices as well as its Quality Assurance System.

This is the new site which was last inspected by WHO Prequalification Team in August 2012. This is the second WHO Prequalification inspection of MEDS.

There is a Quality Management System in MEDS that was certified as ISO 9001:2008 compliant in December 2012.

Focus of the inspection

The inspection focussed on the quality management system and physical, chemical and instrumentation sections as the areas of quality control testing prequalified by the WHO.

It was noted during the inspection that laboratory analyses only finished pharmaceutical products; there was no facility available for storing stability samples. Also, raw materials were not analysed by MEDS.

Inspected Areas

The inspection focused on the quality management system of the laboratory and its analytical activities for physical/chemical (identification, assay, impurities, and related substances using UV-VIS, HPLC, GC, and IR). The requirements of the WHO Good Practices for Pharmaceutical Quality Control Laboratories (Annex 1 of TRS 957) is covered in the inspection were as follows:

- Organization and personnel
- Quality management
- Premises and Equipment
- Documentation
- Sample flow and sample storage
- Reagents and reference substances
- Traceability
- Safety

List of persons (and their positions) met during the opening/closing meeting

- Dr Jane Masiga, Head, Operations
- Mr Stephen Kigera, QA Manager
- Mr Joseph Thuranira, Lab Supervisor
- Mr Wycliffe Nandama, Procurement & Inventory Manager

2.1 Organization and management

The laboratory had managerial and technical personnel with authority and resources needed to carry out their duties which were verified through respective job descriptions of Head Operations, QA Manager and Laboratory Supervisor. The laboratory also had an organization chart which provided relationship between management, technical operations and quality management system. The laboratory also identified and designated QA Manager who ensures compliance with the quality management system.

2.2 Quality management system

The laboratory had a quality management system consisting of various procedures and work instructions. The laboratory had a Quality Management System (QMS) which was organized into organizational structure, processes, procedures, work instructions & resources needed to implement quality management. The QMS system also included Quality Manual, Quality Policy & Quality Objectives to ensure quality in all that is done in the organization.

The Quality Manual was divided into seven processes (core functions) & six support functions. Each process has QMS documents:

- Procedures – specified way to carry out an activity or process
- Work instructions – detailed instructions of how to perform tasks
- Records – forms that are filled that are evidence of activities or tasks performed
- Support functions – work instructions, forms & records

In general, the quality manual was found to be adequate and covered essential Requirements as laid down under WHO and ISO.

2.3 Control of documents

The laboratory maintained documentation in the form of standard operating procedures, work instructions, forms, analytical/validation reports, raw data (electronic and in hard copy), logbooks/registers and spread sheets.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.4 Records

The laboratory established and maintained procedures for identification, collection, retrieval, storage, maintenance and disposal of records as evident from the review of several procedures (document control procedure, SOP on SOP). Upon reviewing of analytical worksheets, it was noted that original observations, calculations, data derived from various instruments & systems were retained on record. The analytical

worksheets and certificate of analysis reviewed were found to be legible, readily retrievable, stored and retained within facility.

2.5 Data-processing equipment

The computer system used with HPLC systems were appropriately qualified by respective instrument vendors.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.6 Personnel

The laboratory has ten personnel including the QA Manager and the Head of Operations with the necessary education, training, technical knowledge and experience for their assigned functions.

The selected staff for internal auditors were trained by the consultant and a written examination was conducted and trainees were assessed.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.7 Premises

The laboratory was found to be clean and tidy at the time of inspection.

The laboratory facilities were found to be of a suitable size, construction and location to support the adequate conduct of the laboratory's activities. The environmental conditions, including lighting, energy sources, temperature and humidity were appropriate to the functions and operations to be performed. These were monitored and controlled in the necessary areas. The storage facilities within the laboratory were well organized for the correct storage of samples, reagents and equipment.

2.8 Equipment, instruments and other devices

The laboratory had the required test equipment, instruments and other devices for the correct performance of the tests and/or calibrations, validations and verifications in general.

The laboratory was equipped with several equipment and instruments such as two dissolution apparatus, analytical balances and six HPLC systems (one out of order at the time of inspection). The laboratory has not been using Gas Chromatogram (GC) since 2012 and it is to be removed from the list of equipment. Once the laboratory has repaired and re-qualified GC equipment, they may submit documentation showing that it has been repaired and re-qualified. The HPLC system make of Shimadzu and Agilent were used with respective software.

The calibration record of dissolution apparatus was reviewed and noted that dissolution apparatus was calibrated using Prednisone USPRS tablet and mechanical calibration included temperature, RPM, wobble and height.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.9 Contracts

An SOP on selection of suppliers and services was in place. It was noted that equipment and instruments were calibrated & maintained by the vendors of these equipment/instruments. The reference standards were procured directly from the USP (United States Pharmacopeia).

The laboratory signed contracts with clients such as USAID who pay after testing was completed whereas other customers who are not on contract, had to pay before testing.

It was noted that though most of the tests were performed by MEDS, some of the tests such as microbiological tests were outsourced to NQCL and or an ISO accredited laboratory within Kenya.

2.10 Reagents

There were no SOP or work instructions available for the preparation and standardisation of reagents and volumetric solutions. It was noted that current pharmacopoeia was referred to, as and when solutions were prepared and standardized. A separate log was not maintained for the preparation and standardization of volumetric solutions and reagents these solutions were prepared on need basis, therefore preparation and standardization details were part of the analytical worksheet.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.11 Reference substances and reference materials

The reference standards used were of acceptable quality. It was noted that laboratory did not prepare working standards and use reference standards from USP. In addition, working standards from manufacturers were received along with samples and used for analysis.

A usage log was maintained for all of the reference standards.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.12 Calibration, verification of performance and qualification of equipment, instruments and other devices

There was a calibration and verification program in place for the laboratory equipment and instruments.

The analytical balances were calibrated once every year and also verified on a daily basis using 20gram weight. The calibration of the balances was done by an outside laboratory, which covered weights from 1mg to 220gram.

The Grade A glasswares were used in the laboratory and certificate for one of the glassware was presented upon request. It was noted that glasswares such as bulk pipette (20ml) were calibrated by KEBS.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.13 Traceability

The result of an analysis was traceable to a reference substance through the reference standard logbook. Calibrations and qualifications of instruments were traceable to suitable reference materials.

2.14 Incoming samples

The samples were received in a receiving room and logged in a sample log. The sample log was divided into internal samples received from MEDS and customers who brought in with request to conduct testing. The samples were stored in a controlled area with a limit between 9°C to 25°C.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.15 Analytical sheet

Analytical worksheets were filled and used.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.16 Validation of analytical procedures

It was noted that pharmacopoeial methods were used by the laboratory. As review of analytical worksheets revealed that some of the test parameters were changed by the laboratory from the recommended pharmacopoeial requirements, such changes were not supported with any verification or revalidation of analytical methods.

The observations raised from this section have been addressed satisfactorily, and will be verified during future inspections.

2.17 Testing

The samples were tested in accordance with the work plan of the laboratory after completion of the preliminary procedures. The laboratory uses current edition of the USP for testing of various samples. The system suitability test was performed as per the pharmacopoeial requirements.

2.18 Evaluation of results

Analytical worksheets were reviewed by the laboratory supervisor and signed off by QA Manager. The out of specifications (OOS) were reviewed by the laboratory supervisor and QA Manager.

An SOP on OOS was in place. A log of OOS was maintained by the laboratory which provided overview of registration number, item description, manufacturer, test and client. Handling of OOS could be improved by including appropriate investigation at all stages.

2.19 Certificate of analysis

Certificates of analyses were acceptable in general. Certificate of analysis was reviewed and noted that most of the information were available in the COA as recommended in WHO guideline.

2.20 Retained samples

Depending on the storage conditions; retention samples were stored in the laboratory. In most of the cases, samples are retained for 2 years after the expiry period. The temperature and humidity in the area for storage of retention samples was controlled, monitored and recorded.

2.21 Safety

The laboratory provided an emergency shower and eye washer for the analysts.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken and planned, **Mission for Essential Drugs and Supplies (MEDS), Nairobi, Kenya** was considered to be operating at an acceptable level of compliance with in compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the laboratory, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.