



WHO PUBLIC INSPECTION REPORT

(WHOPIR)

Quality Control Laboratory

Part 1: General information

Name of QC Laboratory	Laboratory of the Mission for Essential Drugs & Supplies (MEDS)		
Physical address	Along Mombasa Road, Mavoko County, Kenya Mailing address and other contact info: P.O. Box 78040 – 00507 Viwandani Nairobi, KENYA Tel: Switchboard: 3920 000 Wireless: 020-212 4453, 212 4455, 246 0022, 253 2214, 253 2216 Mobile: 0722-202 106, 0726-937 222, 0734-600 310 Fax: 3920 600 Website: www.meds.or.ke		
Contact person and email address.	Jane Masiga (Head of Operations) e-mail: jmasiga@meds.or.ke		
Date of inspection	27 – 28 August 2012		
Type of inspection	Routine		
Type(s) of testing included in the inspection	Chemical and physical		
Summary of the testing activities performed by the QC Laboratory	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
	Physical/Chemical analysis	pH, loss on drying, water content, conductivity, refractometry, friability, disintegration, dissolution, density, uniformity of dosage unit (mass, content)	pH, loss on drying, water content, conductivity, refractometry, density
	Identification	HPLC (UV-VIS detection), UV-VIS spectrophotometry, TLC, chemical reaction	HPLC (UV-VIS detection), UV-VIS spectrophotometry, TLC, chemical reaction
	Assay, impurities	HPLC (UV-VIS	HPLC (UV-VIS

	and related substances	detection), UV-VIS spectrophotometry, volumetric titrations, polarimetry, Determination of related substances/impurities and degradation products	detection), UV-VIS spectrophotometry, volumetric titrations, polarimetry Determination of related substances/impurities and degradation products
	Microbiological tests	N/A	N/A
	Stability studies	N/A	N/A

Part 2: Summary

General information about the company and site

The Mission for Essential Drugs and Supplies (MEDS), Kenya had recently commissioned a new site, in October 2011. It is held as a joint trust of the Christian Health Association of Kenya (CHAK) and Kenya Episcopal Conference (KEC).

The organization was started in 1986 as an ecumenical partnership to improve accessibility to quality health care. The objectives of the organization are to provide a reliable supply of good quality essential drugs and medical supplies at affordable prices as well as to improve the quality of patient care through training in all aspects of health and general management with specific emphasis on the essential drugs concept and rational use of drugs.

MEDS consisted mainly of a warehousing unit which stocked over 900 items and was a distributor of medicines which had the capacity to meet over 40% of Kenya's needs. It also performed quality insurance inspections of manufacturers and commodities as well as testing of pharmaceuticals for both products received at the warehouse and for outside parties.

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.

The new site had not been inspected as of yet.

The inspection focused on all relevant chapters of the WHO guideline with impact on the quality of test results were inspected in detail; including organization and management, quality management system, documentation system including records and analytical work sheets, data-processing equipment, personnel, premises, equipment and measuring devices, contracts, reagents, reference substances, traceability, sample management, method validation, testing and evaluation of test results, the generation and review of certificates of analysis. Please refer to respective headings for detailed information.

Inspected Areas

Day1

After introductions, the company presentation and a brief site tour, inspectors proceeded to a review of the CAPAs to the previous WHO inspection. Other documents reviewed included:

- SOPs for deviations, OOS, SOP, change controls, internal audits
- Job descriptions and organization chart
- Training records
- Management reviews and meetings
- SOP for CAPAs
- Incoming samples

Day 2

Inspectors visited the laboratory and inspected:

- HPLC
- Reference standard storage
- Retention sample storage
- Dissolution
- UV-visible spectrophotometry
- GC

The inspection of the equipment included the computerized systems associated with the HPLC and UV spectrophotometer. Instrument calibration, qualification and performance verification were covered.

The refrigerator for storage of reference standards and the retention samples store were also inspected.

Microbiological testing was not being performed by the laboratory.

2.1 Organization and management

The job descriptions inspected were signed off by analysts, the senior laboratory analyst and quality assurance manager in February 2012.

2.2 Quality management system

The laboratory had a quality management system consisting of various procedures and work instructions.

Internal audits: Internal audit results were discussed during management meetings as per the minutes shown to inspectors.

Deviations: the procedure for deviations OPE-QC-026 was reviewed. It stated that deviations should be reviewed periodically to assess any trends. It also stated that if the request is accepted, the corrective actions to prevent future recurrence should be documented and implemented. Issues raised during the inspection were resolved in the company CAPAs.

CAPAs: SOPs were revised further to the inspection and are now acceptable.

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.

2.4 Records

Records were at times difficult to retrieve. Further to the inspection, improvements were made to the indexing, storage and maintenance of and access to all quality and technical scientific records.

2.5 Data-processing equipment

Computers used to process HPLC data and UV data are now locked. This issue was addressed in the company CAPAs for all computerized systems at the site.

2.6 Personnel

The laboratory had a small personnel component consisting of only 3 analysts, a QC manager and a QA manager. The QA manager was being transferred to another section and a new QA manager was appointed a couple of months prior to the inspection.

Attention should be paid to ensure that the number of quality control analysts present at the laboratory is sufficient to accommodate all activities being done.

Training: the identification of the training needs for new employees would need to be strengthened.

2.7 Premises

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 set location of storage for the refrigerated samples was not clear as different locations were possible (either in the warehousing area or within the laboratory). Nevertheless, the storage facilities within the laboratory were well organized for the correct storage of samples, reagents and equipment. The main refrigerated storage unit has been calibrated by an external body, Kenya Bureau of Standard, and temperature alert mechanism installed. MEDS has placed an order for data loggers and temperature mapping will start in the month of May 2013.

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 GC equipment was out of use at the time of the inspection.

2.9 Contracts

This area was not inspected.

2.10 Reagents

The reagents seen were purchased from reputable suppliers, however the date of opening was not always correctly written on the labels.

2.11 Reference substances and reference materials

The reference standards used were of acceptable quality. This area was not inspected in detail.

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

Suitable equipment calibration and performance verification was performed.

2.13 Traceability

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

2.14 Incoming samples

Procedure OPE-QC-003 dated 28 February 2011 was used for Sample Handling. Incoming samples were recorded under 2 different registers, one for MEDS QC warehouse samples and another one for contracted tests. Issues raised about the registers were addressed in the company CAPAs to a satisfactory level.

2.15 Analytical sheet

Analytical worksheets were filled and used but lacked information on the method and the preparations in the examples which were inspected.

2.16 Validation of analytical procedures

Issues were noted with regards to method transfers, method verification or validation but were addressed in the company CAPAs.

2.17 Testing

The manner in which HPLC testing was done was recently harmonized with current requirements. Adequate system suitability testing and validation or method verification was added. And the actual test procedures followed are now described in sufficient detail and deviations relative to the pharmacopoeial methods are assessed and treated as per the deviation procedure.

2.18 Evaluation of results

The way in which evaluation of test results is done was improved through the laboratory's CAPAs. did not include a review of whether the analysis fully complied with repeatability system suitability requirements or a review of the sequence that was followed.

Audit trail are now used to independently capture the time and date of operator entries and actions that create or modify electronic records.

2.19 Certificate of analysis

Certificates of analyses were acceptable in general but this area was not inspected in detail.

2.20 Retained samples

The temperature and humidity in the area for storage of retention samples was controlled, monitored and recorded. It was considered to be acceptable.

2.21 Safety

Safety was not considered during this inspection due to time constraints.

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, the ***Laboratory of the Mission for Essential Drugs & Supplies (MEDS), Kenya***, was considered to be operating at an acceptable level of 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.