World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the Quality Control laboratory
(WHOPIR)

Part 1	**General information**		
Laboratory Details			
Name of the laboratory	TMDA Quality Control Laboratory Directorate of Laboratory Services (DLS)		
Address of inspected laboratory	Off-Mandela Road, Mabibo-External P. O. Box 77150 Dar Es Salaam Tanzania Website: www.tmda.go.tz		
GPS Coordinates	Latitude: -6.8076 Longitude: 39.2134		
Inspection Details			
Dates of inspection	25 – 28 May 2021		
Type of inspection	Follow-up QCL inspection		
Introduction			
Brief description of testing activities	*Type of analysis*	*Finished products*	*Active pharmaceutical ingredients*
	Physical/ Chemical analysis	pH, melting point, optical rotation, conductivity, friability, tablet hardness, disintegration, dissolution, uniformity of dosage units	pH, melting point, optical rotation, conductivity
	Identification	HPLC (UV-VIS, PDA detection), TLC, UV-VIS Spectrophotometry, FTIR (Perkin Elmer FTIR)	HPLC (UV-VIS, PDA detection), TLC, UV-VIS Spectrophotometry, FTIR (Perkin Elmer FTIR)
	Assay, impurities and related substances	HPLC (UV-VIS, PDA detection), TLC, UV-VIS Spectrophotometry, polarimetry, volumetric titration	HPLC (UV-VIS, PDA detection), TLC, UV-VIS Spectrophotometry, polarimetry, volumetric titration

	Micro-biological tests	Microbial Limit Test, Bacterial endotoxin test (LAL), bioassay	Microbial Limit Test, Bioassay
General information	The TMDA Quality Control Laboratory, formerly known as TFDA Laboratory was established under section 14 (1) of the Tanzania Medicines and Medical devices Act, Cap. 219 to carry out the analysis of regulated products. The laboratory forms the Directorate of Laboratory Services which is among the three (3) directorates of the Tanzania Medicines and Medical Devices Authority (TMDA). The Authority underwent a reorganization in July 2019. TMDA is under the ministry of Health, Community Development, Gender, Elderly and Children. It is responsible for controlling the quality, safety, efficacy of medicines, medical devices, diagnostics, biocidals and tobacco products.		
History	Physico-chemical and Microbiological testing sections of the laboratory were previously inspected by WHO Prequalification Inspection Services on 9 - 12 Apr 2019. A follow-up inspection was recommended to verify the implementation of the respective CAPA plan. The observations were generally addressed, and the evidence of implementation of CAPA plan was provided.		
Brief report of inspection activities undertaken – Scope and limitations			
Areas inspected	A follow-up inspection was performed to verify the corrective and preventive actions related to the deficiencies raised during the April 2019 PQ inspection. The following areas were inspected: a) Microbiology laboratory and the respective activities b) Pharmaceutical quality system c) Calibration and qualification documentation d) Qualification of computerized systems e) Equipment qualification f) Premises g) Reagents and reference standards h) Documentation & records		
Restrictions	Travel restrictions during the COVID-19 pandemic had noticeable impact on procurement of services, devices and equipment.		
Out of Scope	The HVAC system in Microbiology Premises for sterility test was not operational. The system was impaired due to a high voltage stream caused by some problems in the public power supply. The maintenance service was ordered through a Chinese service provider. However, it had to be deferred due to pandemic state. The facility was not in a state to be inspected. Hence, the sterility testing activity was removed from the scope of the inspection and it		

	will be requested to be withdrawn from the list of Prequalified Laboratory's activities.
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
CAPA	Corrective action & Preventive action
DQ	Design qualification
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GC	Gas chromatography or Gas chromatography equipment
GMP	Good manufacturing practices
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
IQ	Installation qualification
IR	Infrared spectrophotometry
KF	Karl Fisher titration
LIMS	Laboratory information management system
LQO	Laboratory quality officer
MB	Microbiology
MR	Management review
N	Normality
NC	Non-conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
OQ	Operation qualification
Ph.Eur.	European Pharmacopoeia
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PT	Proficiency testing
PTS	Proficiency testing scheme
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QM	Quality manual
QMS	Quality management system

QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure
TLC	Thin layer chromatography
TOC	Total organic carbon
URS	User requirements specifications
USP	United Stated Pharmacopoeia
UV	Ultraviolet-visible spectrophotometry or spectrophotometer
VMP	Validation master plan
VS	Volumetric solution

Part 2	**Summary of findings and recommendations**

1. Organization and management

The organization and management structure of the laboratory; including responsibility, authority and interrelationship of the personnel were specified in the organizational chart. The laboratory was headed by Dr Danstan Hipolite. The laboratory had undergone a restructuring and was organized into three sections:

- Medicines and Complementary Product analysis
- Medical Devices Analysis
- Microbiology analysis

The general working hours were from 7:30 am to 3:30 pm.

2. Quality management system

A quality management system was established, implemented and maintained appropriate to the scope of the Laboratory's activities, including the type, range and volume of testing and/or calibration, validation and verification activities it undertook. The deficiencies observed during the previous inspection were adequately addressed.

Risk management plan / risk register on the applicable form was provided. A systematic process of organizing information to support a risk decision to be made within a risk management process was implemented. It consisted of the identification of hazards, as well as the analysis and evaluation of risks associated with exposure to those hazards.

Trend analysis was addressed in the respective SOP. Guidance on trending of data obtained from PTS results, suppliers' performance, purified water quality, selected equipment / instrument performance reports, environmental monitoring records, risk management, non-conformities, management review and OOS was implemented. Trend analysis report for evaluation of water quality monitoring, balance verification and operational performance of HPLC, prepared in May 2021, was reviewed.

Proficiency testing

The control laboratory participated in suitable proficiency testing schemes to assess analytical procedures or reference substances. The proficiency testing schemes and the evaluation of the Laboratory's performance, together with the outcome of respective investigations were reviewed and discussed. PTS Participation Plan for 2019, 2020 and 2021 was reviewed. The last participation in a Proficiency Testing Scheme was recorded in 2020, as several issues related to the administrative process for the payment of services provided by EDQM and Pharmassure were raised.

Internal audit

The activities of the Laboratory were systematically and periodically audited to verify compliance with the requirements of the quality management system and to apply corrective and preventive actions, if necessary. The audits were carried out by trained and qualified personnel, who were independent of the activity to be audited.

The quality manager was responsible for planning and organizing the internal audits addressing all elements of the quality management system.

The records of the internal audits from September 2020, for both units, together with details of any corrective and preventive action taken were reviewed and discussed.

Complaints

The applicable SOP described the acceptance, handling, recording and closing of any complaint or compliment from a customer. A complaint register for a randomly selected complaint, from a manufacturer which disagreed with the test results issued by the laboratory, was reviewed.

Management Review

The management review of quality issues had not taken place since the previous WHO inspection, i.e. April 2019. The respective SOP was discussed with the QA-management to identify the possibilities to improve the management review's process. It was highlighted that the outcome of investigations which were carried out as a result of risk identification and trend analysis, should be implemented in accordance with the respective SOP. The SOP should also be followed during the preparation of the management review.

Change Control

The Laboratory's change control system was evidently implemented. The evidence of training of applicable staff was provided through the respective compliance report in respect to the previous WHO inspection.

Randomly selected records were reviewed during the inspection.

Handling of deviation / non-conformities

SOP for Handling of deviations and SOP for Handling of non-conformities were implemented. Respective master lists for 2019, 2020 and 2021 were available, per laboratory section and QA.

The quality manual approved on January 2021 defined that non-conformities and recommendations, raised by external assessors, would be dealt using the original CAPA documents, without being recorded on the non-conformities master list (item 2.2.1.9.7).

Randomly selected records were reviewed during the inspection.

The identified deficiencies related to the QMS were adequately addressed in the Laboratory's CAPA plan.

3. Control of documentation

The laboratory had established and maintained a system of procedures to control all documents (preparation, revision, distribution, return, archiving). A master list identifying the current version status and distribution of documents was available. Each document controlled had a unique identifier, version number, date of implementation, reference to the previous version. The documents were released by the quality manager and available at the relevant location. Staff was trained on new and revised SOPs. The personnel acknowledged by signature that they were aware of applicable changes.

Copy of templates were issued by LQO with a unique identifier that could be traced to the logbook for "System forms / register Distribution" which was used for issuance of templates. Document reconciliation was checked and the traceability between copies was ensured.

An identified deficiency related to the control of documentation was adequately addressed in the Laboratory's CAPA plan.

4. Records

Record were made of analytical tests, including calculation and derived data, method validations/ verifications, instrument use, calibrations and maintenance and sample receipt in analyst notebooks containing consecutively numbered pages and the laboratory's e-LIMS. The records were signed, and alterations were commented. Records were kept in an archive for a period of shelf-life plus one year for a pharmaceutical product on the market.

Access to the archive was restricted to a list of authorized personnel which was displayed on the entrance of archive facility. Fireproof cabinets were provided in order to prevent early destruction of the documentation. The temperature and humidity of the archive facility was properly monitored.

All data, including both paper and electronic versions, were organized to ensure their easy retrieval and traceability. The archive processes were tested through the successful recall of requested documents and records during the conduct of the inspection and found effective.

The identified deficiencies related to the records were adequately addressed in the Laboratory's CAPA plan.

5. Data processing equipment

An inventory of all computerised systems with the information about unique identification, software system's version, purpose, validation status, and the respective revalidation plan was available.

Following software systems were investigated to ensure the validation of the system, including the application of respective audit tail function:

- LIMS
- LabSolution (Shimadzu HPLC)
- OpenLab (Agilent 1260 HPLC)
- Perkin Elmer Spectrum IR ES, (Perkin Elmer FTIR)
- LabSolution (Shimadzu UV-3600 UV-Vis)

Records on URS, installation, operation and performance qualification (incl. updates) were provided and kept for computerised systems which were components of test equipment. Electronic data was protected from unauthorized access.

LIMS software system developed by the vendor was documented in sufficient detail and appropriately validated or verified as being suitable for use. The validation of the software system was completed on Mar 2021.

Procedures were established and implemented for protecting the integrity of data, including measures to ensure the integrity and confidentiality of data entry or collection and the storage, as well as transmission and processing of data. All the software systems were equipped with adequate audit trail function to maintain all the data amendments.

The access rights and the associated privileges were defined in the applicable SOP and subsequently implemented.

Electronic data was backed up at appropriate regular intervals according to a documented procedure. The restoration process of data had just started since May 2021. Date & time of workstations, as well as the USB ports were deactivated and could only be changed by the designated IT-personnel.

The identified deficiencies related to the data processing equipment were adequately addressed in the Laboratory's CAPA plan.

6. Personnel

The laboratory's personnel had generally remained the same.

The identified deficiency related to the personnel was adequately addressed in the Laboratory's CAPA plan.

7. Premises

The laboratory facilities had undergone a refurbishment to improve the design to suit the functions and the operations.

The environmental conditions of required rooms were adequately monitored and controlled.

Gases were stored in a dedicated area, isolated from the main building. However, they were detached since the Laboratory did not use the Atomic Emission Spectrometer (AES) for any testing.

The laboratory provided separate rooms for storing flammable substances, fuming and concentrated acids and bases. Flammable chemicals were properly stored in new designated cabinets in the storage for liquid chemicals.

Access to the laboratory facilities was restricted to designated personnel by using biometric and/or key-card control systems.

Microbiology laboratories and certain support equipment (e.g. autoclaves and glassware) were dedicated and separated from other areas. Sufficient space for all activities to avoid mix ups, contamination and cross-contamination was considered in design of the microbiology laboratory.

Due to malfunction of separate air supply (HVAC system) in the laboratory, the adequate control of contamination, temperature and humidity required for sterility testing was not achievable. Hence, the air supplied to the laboratory could not be of appropriate quality and could be considered as a source of contamination. The service of the HVAC system was not performed due to the COVID-19 related travel restrictions. Subsequently, an appropriate area-classification of the microbiology laboratory used for the sterility testing was not available. Hence, the inspection team considered the sterility testing excluded from the scope of inspection.

The identified deficiencies related to the premises were adequately addressed in the Laboratory's CAPA plan.

8. Equipment, instrument, and other devices

The equipment, instruments and other devices used for the performance of tests, calibrations, validations, and verifications were required to undergo a successful calibration/validation/qualification procedure before being approved for usage.

The maintenance of a few equipment in the laboratory was delayed due to the COVID-19 pandemic situation. There were two autoclaves in the Microbiology laboratory, one of which was under maintenance. Therefore, the autoclave uniclave 77 was used for both sterility and decontamination activities, by running one empty cycle after each decontamination activity. The logbook for usage of autoclave was reviewed and the activities were verified.

For more details, refer to section 12.

9. Contracts

The laboratory had a procedure in place for the selection and purchasing of services and supplies.

The signed contracts defined the contracted work and established duties and responsibilities for each party. The competence of the contracted organizations was assessed, and records of these assessments were kept in accordance with SOP for Procedure for purchasing of Services and Supplies.

The identified deficiencies related to the contracts were adequately addressed in the Laboratory's CAPA plan.

10. Reagents & Media

The reagents used were of appropriate quality and correctly labelled. Labels of reagent contained: content, manufacturer, date received and date of opening of the container, concentration, if applicable, storage conditions, expiry date and retest date, as justified.

Reagent solutions prepared in the laboratory were also properly labelled with information about name of the reagent, date of preparations and initials of technician or analyst, expiry date or retest date, as justified, concentration, if applicable.

Volumetric solutions were labelled in the laboratory with information about name, molarity, date of preparation and initials of technician, date of standardization and initials of technician, standardization factor.

The quality of water was verified regularly (microbiology, pH and conductivity) to ensure that it met the appropriate specifications. This verification was subjected to trend analysis.

Media were purchased in original containers from qualified vendors with adequate certifications. Growth promotion were required to be carried out on all media on every batch and on every shipment. The activity was documented in the analyst logbook, together with reference to the logbook for media preparation and cultures used for performance verification.

The procedure for suitable performance of culture media, diluents and other suspension fluids was implemented. Water of a suitable microbiological quality, free from bactericidal, inhibitory or interfering substances, was used for preparation unless the test method specifies otherwise.

Repartition of media after sterilization was performed under unidirectional airflow to minimize potential for environmental contamination.

Batches of media were identifiable and their conformance with quality specifications was documented. Media were prepared in accordance with any manufacturer's instructions. There were no microwave devices to indicate that the device had been used for the melting of media.

Logbook for culture media / water, reagents preparation was used to record the preparation of media. All information about parameter, activity (e.g. culture verification and resuscitation, reference culture), detail of water used in media preparation, equipment and media preparation was adequately recorded. The overview over the media stock was kept in an Excel sheet where the usage was recorded. The prepared media could be linked to a reference number / identification number used for the respective reference culture.

The identified deficiencies related to the reagents and media were adequately addressed in the Laboratory's CAPA plan.

11. Reference substances and reference materials

a) Reference substances and reference materials

Reference substances were purchased from approved vendors and stored in the required condition either in a desiccator or a refrigerator, and periodically monitored according to the following provisions:

- Instructed by manufacturer
- Verification of USP Reference standards retest date provided on the USP website, prior to each use
- Verification of the Batch Validity Statement (BVS) provided on the EDQM website for EPCRS and ICRS, prior to use.

The respective SOP was reviewed and contained the necessary information to comply.

Official pharmacopoeial standards were mostly used for the purposes described in the corresponding monographs. Adequate information was kept on the labels of reference substances. CoAs of Reference standards were available. An identification number was assigned to all reference standards and a person was nominated to be responsible for the Reference Standards. An issue log was kept, in which the required information was recorded.

b) Reference cultures

Reference cultures were available for establishing acceptable performance of media, for validating methods, for verifying the suitability of test methods and for assessing or evaluating ongoing performance. Reference strains of microorganisms were obtained directly from a recognized supplier.

The reference stocks provided from reference strains were stored in aliquots deep-frozen in a -80°C freezer. Working cultures for routine use were primary subcultured from the reference stock and stored in -20 °C designated freezer.

Working stocks were normally subcultured only once from the primary reference culture. The Laboratory's practice did not allow to prepare the working stocks more than five generations (or passages) from the original reference strain.

The form for Reference Microorganisms Register with information about date of receipt, culture name, ATCC no, batch lot, expiry date, availability of certificate and the storage condition of stock samples, ID number of vials (1-5) and primary samples, as well as signatures and remarks were available.

Performance of primary cultures was verified monthly and documented on the respective template, i.e. Maintenance of reference microorganism cultures.

At the time of inspection, the refrigerator and freezer used for storage of cultures was under maintenance. Therefore, all the primary stock had been discarded and new primary culture preparation was in process.

The identified deficiencies related to the reference substances and reference materials were adequately addressed in the Laboratory's CAPA plan.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

Each instrument was uniquely identified. Labels indicated the status of the calibration and the date when recalibration was due. Equipment underwent DQ, IQ, OQ and PQ, following a plan established by the laboratory. A new identification numbering system was in process to be implemented from July 2021. Hence, the equipment certifications were issued using the former identification number.

The serial number could be used to track down the equipment's identification. The equipment was labelled with both the former and the new identification number.

Balances were calibrated on annual basis by an external calibration service provider. The balances were assessed for accuracy, precision, linearity and eccentricity. They were checked weekly using five different test weights, across the working range of each balance. The standard weights were calibrated after the annual calibration with certified reference weights. A study on the stable behaviour of the balances was provided thru the trend analysis report, dated May 2021.

Records/logbooks were kept for items of equipment with information to identify the device, maintenance carried out, history of damage, malfunction, modification or repair. Use of the instrument was also recorded.

The following equipment were selected to verify the adequacy of calibration/validation certificates with respect to the deficiencies identified during the previous WHO inspection. The respective SOPs for Operation, verification and cleaning were also reviewed:

- Biosafety cabinet was qualified by external state service provider in accordance with the respective protocol, i.e. Biosafety cabinet performance qualification protocol.
  Viable particle verification of the biosafety was done using air settlement plates during the sample analysis. The procedure was described in the SOP for Operation, verification, qualification and cleaning of HEPA safe biosafety cabinet.
- Incubator 37°C
- Uniclave 77 autoclave. The Laboratory did not have a separate autoclave for decontamination and sterilization activities. In exceptional cases, one autoclave may be acceptable provided that extensive precautions are taken to separate decontamination and sterilization loads, and a documented cleaning programme is in place.
  The laboratory had two autoclaves, but one of them was under maintenance. The equipment was properly labelled as "Under Maintenance". Separation of sterilization and decontamination activities were separated by time: An empty cycle was executed between sterilization and decontamination processes. The practice was recorded as "Decontamination & Empty cycle" on the form for equipment use log sheet for the respective autoclave.
- Disintegrator Erweka ZT53
- FTIR Perkin Elmer Frontier
- Balance Mettler Toledo XP205
- Balance Shimadzu AUW RO
- pH meter and condutivimeter Mettler Toledo
- Friabilometer Copley

The identified deficiencies related to the equipment were adequately addressed in the Laboratory's CAPA plan.

13. Traceability

Traceability of test results was provided by recording the applicable identification numbers in the LIMS.

Calibrations or qualification of instruments were generally traceable to certified reference materials and to SI units (metrological traceability)

The identified deficiencies related to the traceability were adequately addressed in the Laboratory's CAPA plan.

14. Incoming samples

This part was previously inspected, and all deficiencies were adequately addressed.

15. Analytical worksheet

Information about samples, test procedures, calculations and results were recorded in analytical worksheets (Analyst notebook) which were completed by raw data. Analytical worksheets from different units related to the same sample were assembled.

Reference to specifications and description of the test methods, by which the sample were tested, including the limits; identification of test equipment used; reference substances, reagents and solvents employed was made in the analyst notebook and the analytical worksheet module of the LIMS.

The analyst notebooks contained the following information:

- the date on which the analysis was started and completed;
- interpretation of the results and
- the conclusion whether the sample was found to comply with the specifications.

All graphical data, whether obtained from recording instruments or plotted by hand, were attached or were traceable to the electronic record file or document where the data was available.

The completed analytical worksheets were signed by the analyst and verified, approved and signed by the supervisor. For corrections, the old information was deleted by putting a single line through it; so, it was not erased or made illegible. Alterations were signed by the person making the corrections and dated when the changes were inserted.

The identified deficiencies related to the analytical worksheets were adequately addressed in the Laboratory's CAPA plan.

16. Validation of analytical procedures

The procedures employed for testing were suitable for the intended use, as demonstrated by validation, if appropriate. When pharmacopoeial methods were used for a FPP for the first time, it was demonstrated that no interferences arose from the excipients present. For an API, it was demonstrated that impurities coming from a new route of synthesis were adequately differentiated. Although the pharmacopoeial method was adapted for another use, it was further validated for such a use to demonstrate that it was fit for purpose.

Appropriate system suitability tests were employed prior to the analytical tests for verification of pharmacopoeial methods and/or validated analytical procedures.

The identified deficiencies related to the validation and verification of analytical methods were adequately addressed in the Laboratory's CAPA plan.

17. Testing

The laboratory was required to use the most current pharmacopeial edition as testing method, although the respective edition was not specified in the test request. The methods were described in detail to allow analysts to perform the analysis in a reliable manner. Specific tests were carried out by specialized external laboratory. A list of authorized laboratories was available.

Seven randomly selected testing, as well as their respective OOS investigations (if appliable) were reviewed.

The identified deficiencies related to the testing were adequately addressed in the Laboratory's CAPA plan.

18. Evaluation of test results and OOS investigation

An SOP was in place describing the conduct of OOS investigations. When a doubtful result (suspected OOS result) was identified, a review of the procedures applied during the testing process was undertaken by the supervisor and the analyst.

Doubtful results were rejected only if an error could clearly be identified.

If the investigation was inconclusive, the SOP gave clear guidance on the number of retests allowed (based on statistical principles). Once an error was identified, corrective and preventive measures were recorded and implemented. All individual results (all test data) with acceptance criteria were reported. The repeat of tests was done by a second analyst, as experienced and competent as the first one.

Analytical test reports were issued by the laboratory based on information recorded in analytical worksheets. When investigative testing was performed, the estimated uncertainty of quantitative results was also given (not relevant for tests according to pharmacopoeias or tests which are part of the official release tests).

The test reports further included the following information:

- the background and the purpose of the testing;
- reference to the specifications and methods used;
- the results of all tests performed (or numerical result with the SD of all tests performed);
- the statement whether the sample complies with the requirements.

OOS forms recorded for four randomly selected samples were discussed.

The identified deficiencies related to the OOS investigation and analytical test reports were adequately addressed in the Laboratory's CAPA plan.

19. Certificate of analysis

A certificate of analysis was issued in LIMS for each sample/batch of a substance or product and contained series of information, among others:

- Application number;
- Manufacturer, batch number, date of manufacture and expiry date;
- Test parameters;
- Method;
- Specifications;
- Results;
- And finally remarks and conclusion.

For post-marketing surveillance samples, coded as PMS, no CoA was issued through LIMS. The results were reported as "Summary results for PMS Samples (Multiple Certificate of Analysis).

The identified deficiency related to the CoA was adequately addressed in the Laboratory's CAPA plan.

20. Retained samples

This part was previously inspected, and all deficiencies were adequately addressed.

21. Safety

The safety of the laboratory was considerably enhanced. All precaution measures were implemented to handle the chemicals in admissible manner. Eyewash units were properly installed. Safety data sheets were readily available before testing was carried out.

The waste management procedure was also re-inspected.

The identified deficiency related to the Safety was adequately addressed in the Laboratory's CAPA plan.

Miscellaneous	
Assessment of the Laboratory Information File	The Laboratory Information File was revised on March 2021 and contained specific information about the operations being carried out at TMDA QCL and essential steps for each activity were described and where appropriate. Supportive documentation was appended.
Annexes attached	N/A

Part 3 – Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, including the CAPA plan provided for the observations listed in the Inspection Report ***TMDA Quality Control Laboratory***, located at ***Off-Mandela Road, Mabibo-External, Dar Es Salaam; Tanzania*** is considered to be operating at an acceptable level of compliance with WHO GPPQCL Guidelines.

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.

Part 4 List of WHO Guidelines referenced in the inspection report

1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 1.
   Short name: WHO GPPQCL Guidelines or ***TRS No. 957, Annex 1***
   http://www.who.int/medicines/publications/44threport/en/

2. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
   Short name: WHO TRS No. 961, Annex 2
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS No. 1033, Annex 4
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

6. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO GMP guidelines*** or ***TRS No. 986, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

7. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
http://www.who.int/medicines/publications/44threport/en/

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
Short name: WHO TRS No. 961, Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex* 9**
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
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