20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Quality Control Laboratory

Part 1	**General information**		
Inspected laboratory details			
Name of Laboratory	**Pusat Pengembangan Pengujian Obat dan Makanan Nasional (PPPOMN) / National Quality Control Laboratory for Drug and Food (NQCLDF)**		
Address of inspected laboratory site	Medicines and Pharmaceutical Starting Materials Subdivision Jalan Percetakan Negara, No. 23 Jakarta Pusat, 10560, Indonesia		
Inspection details			
Dates of inspection	10-13 January 2023		
Type of inspection	Routine inspection		
Introduction			
Brief description of testing activities	**Type of Analysis**	**Finished Products**	**Active pharmaceutical ingredients**
	Physical/Chemical analysis	pH, water content (KF), Loss on Drying, Dissolution, Uniformity of Dosage (or mass content)	pH, water content (KF), Loss on Drying, Dissolution, Uniformity of Dosage (or mass content)
	Identification tests	HPLC, Spectrophotometry Basic test (TLC, coloring reaction, precipitation reaction)	HPLC, Spectrophotometry Basic test (TLC, coloring reaction, precipitation reaction)
	Assay, impurities, and related substances	HPLC (UV, PDA, Fluorescence, Electrochemical detectors); GC; Spectrophotometry (UV – Vis and FTIR), Volumetric and Potentiometry Titrations, Gravimetry.	HPLC (UV, PDA, Fluorescence, Electrochemical detectors); GC; Spectrophotometry (UV – Vis and FTIR), Volumetric and Potentiometry Titrations, Gravimetry.
	Microbiological	The Medicines and	The Medicines and

	analysis	Pharmaceutical Starting Materials Sub-Division does not perform microbiology testing.	Pharmaceutical Starting Materials Sub-Division does not perform microbiology testing.
	Miscellaneous	Medicines and Pharmaceutical Starting Materials Sub-Division does not conduct stability testing. It does not have a suitable facility and/or equipment for stability testing.	Medicines and Pharmaceutical Starting Materials Sub-Division does not conduct stability testing. It does not have a suitable facility and/or equipment for stability testing.
General information about the laboratory	The Medicines Subdivision of the Physical Chemistry of Medicines, Narcotics and Psychotropic Section within the Therapeutic Product and Hazardous Substances Division (PTBB) for the National Quality Control Laboratory of Drug and Food (PPOMN) of the National Agency of Drug and Food Control (Badan POM) was established in 2001 by Badan POM SK number 02001/SK/KBPOM TAHUN 2001. In February 2018, the name of The Medicines Subdivision of the Physical Chemistry of Medicines, Narcotic and Psychotropic Section within the PTBB Division for PPOMN was changed to Medicines Subdivision within Chemical Division of Medicines, Narcotic, Psychotropic, Precursor, and Addictive Substances (NAPPZA) of PPPOMN". The change was due to regulation POM No. 26, 2017. It is a government laboratory independent of the Indonesian Ministry of Health. The Medicines Subdivision is responsible for providing quality analytical testing of therapeutic medicine to the government of Indonesia in accordance with the Decree of the Head of the National Agency of Drug and Food Control Number HK.04.01.1.22.09.18. 4587-year 2018 which provides for the laboratory to perform testing of drugs and food. In addition to product testing, the Medicines Subdivision is mandated to develop analytical methods and provide training for testing therapeutic products and hazardous substances for 34 provincial quality control laboratories throughout Indonesia. The Medicines and Pharmaceutical Starting Materials Subdivision is located on the 3rd floor of Building 1 of PPPOMN, Badan POM within The Chemical Analytical Development of Medicines, Pharmaceutical Starting Materials, Narcotics and Psychotropic, Precursors and Addictive Substances Division (KOBONAPPZA).		

	According to the provision of POM No. 21, 2020 and degree 02.1.2.12.20.1149, 2020 KOBONAPPZA is divided into two sub-divisions mandated to test items (medicines, narcotic, psychotropic, precursor and addictive substances) under the category of its title; Medicines and Pharmaceutical Starting Materials Sub-division and Sub-division of Narcotic, Psychotropic, Precursor and Addictive Substances. The medicines and Pharmaceutical Starting Materials Subdivision has the responsibility for providing quality analytical testing of the therapeutic product. The laboratory handed tests and testing facilities for cigarette and medical devices over to the investigation laboratory in March 2021, For the analysis of the cigarette product and the preparation were done by investigation laboratory.
History	The National Quality Control Laboratory for Drug and Food (NQCLDF) has been recognized by the Indonesian Accreditation Body (Komite Akreditasi Nasional/KAN) for implementing ISO/IEC 17025 since 1998. Accreditation was concluded on the testing laboratory and calibration instruments. On December 13, 2022, NQCLDF was re-assessed by KAN for surveillance. The Indonesian FDA and all units have been recognized for implementing ISO 9001:2015. On August 18, 2022, NQCLDF was assessed by Sucofindo International Certification Services, with the certificate number QSC 01832. This is the 3rd WHO PQT inspection of the laboratory. The laboratory was inspected in May 2018 and February 2019.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	- Quality Management System - Personnel - Training and safety - Documentation and records - Premises and equipment - Validation, qualification, calibration - Good laboratory practices - Reference standards - Reagents, water
Restrictions	None
Out of scope	The inspection was limited to physical, chemical and instrumentation analysis of finished pharmaceutical products including starting materials.
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GMP	Good manufacturing practices
HPLC	High performance liquid chromatography (or high-performance liquid chromatography equipment)
KF	Karl Fisher titration

LIMS	Laboratory information management system
MB	Microbiology
MR	Management review
NC	Nonconformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometry or spectrophotometer

Part 2	**Summary of the findings and comments**

1. Organization and Management

The organizational structure of Badan POM, PPPOMN and The Chemical Analytical Development of Medicines, Pharmaceutical Starting Materials, Narcotics and Psychotropic, Precursors and Addictive Substances Division (KOBONAPPZA) are addressed in the Quality Manual 100-06, attachment 1, 2 and 3, pages 48-50. The previous name of the laboratory was Chemical Division of Medicines NAPPZA. The current name is Chemical Analytical Development of Medicines, Pharmaceutical Starting Materials, Narcotics, Psychotropic, Precursors and Addictive Substances Division. The laboratory is headed by Mr Mohamad Kashuri, S.Si., Apt., M. Farm whereas the current technical manager is Ms Dra. Mirawati Siregar., Apt, M.Si.

The laboratory is legally authorized to operate and can be held responsible legally. The laboratory is part of Badan POM, the Food and Drugs Administration of Indonesia. The managerial and technical personnel with the authority and resources are described in the laboratory's quality management system.

The deficiencies noted from the organization and management section have been addressed satisfactorily and the same will be verified during future PQ inspections.

2. Quality management system

The primary functions and requirements of the administrative, quality and technical operations of the Medicines and Pharmaceutical Starting Materials Sub-Division are outlined in The Chemical Analytical Development of Medicines, Pharmaceutical Starting Materials, Narcotics and Psychotropic, Precursors and Addictive Substances Division (KOBONAPPZA) Quality Manual. The Chemical Analytical Development of Medicines, Pharmaceutical Starting Materials, Narcotics and Psychotropic, Precursors and Addictive Substances Division (KOBONAPPZA) has established and maintains a quality system to meet the requirements of ISO 9001, ISO/IEC17025, WHO TRS 957, Annex 1, 2010, GPPQCL and national and regional regulatory guidelines.

Quality Manual

The policies, procedures, systems, and programs defined within the quality manual support laboratory activities to ensure the generation of reliable data that complies with the requirements of international standards, internal procedures, and government regulations; Regulation of Indonesian Food and Drug Authority No. 21 year 2020, Decree of the Head of Indonesian Food and Drug Authority and Laws of Republic Indonesia on Health. The quality management system of KOBONAPPZA is documented in 4 level documents, where Level 1 is the Quality Manual that contains all policies and requirements, Level 2 is the Standard Operation Procedure, Level 3 is Work Instruction and Level 4 is Forms used for recording information.

Change Management System

The SOP on changes was discussed and it covered all changes including changes in documents and operating procedures. The review was performed by a verifier and the technical manager and if required the appointment of a multidisciplinary team who assess the impact of the change. The QA had to be part of the team that did the assessment, especially for the risk analysis. Approval was done by the technical manager. A change control number was assigned when a change was raised, and it was well-defined in the operating procedure. Several change controls were evaluated.

Deviation

Handling of deviations was performed according to an SOP. Several deviations were reviewed, and their handling was generally found to be acceptable. A deviation had to be investigated within 30 days and an investigation and impact assessment performed.

Complaint management

The complaint handling procedure was discussed. The procedure was referenced to WHO TRS 957, Annex-1, ISO 17025:2017 and internal reference. The procedure defined the terms such as the complainant, complaint, client, corrective action etc. The complaints were received by the administration department which in turn forwarded the same to the senior management before being investigated by the technical manager. The laboratory confirmed that they had not received any complaint from the Global Fund since 2019. It was noted that the laboratory completed the 2022 customer satisfaction survey, and the laboratory was confirmed as satisfactory.

Investigation

The procedure for conducting investigations was reviewed. It included investigation tools such as a fishbone diagram and 5 Why.

Corrective and Preventative Action (CAPA)

The SOP described that CAPA could be applied to, internal- or external audits, complaints, and deviations to name a few examples. The register and a CAPA form were used to record the non-conformance, category, root cause, CAPA plan, corrective action, preventative action, proposed closed-out date, close-out date and verification date and status. The numbering of CAPAs was adequately defined and sequential in the register.

Quality risk management (QRM)

The procedure for QRM was discussed. A cross-functional team was responsible for performing risk assessments. The risk was assessed based on the identified key performance indicators (KPIs) e.g. service of the laboratory, sample testing and WHO Prequalification of the laboratory. The fundamentals of ICH Q9 were implemented in the QRM procedure and RPN was used to calculate high, medium, and low risk. A risk register was maintained.

Management review (MR)

The procedure for the management review was discussed. The purpose of this procedure was to evaluate the QMS implementation in the laboratory. Top management was responsible for performing the management review whereas QA was responsible for executing this activity. The MR discusses the outcome of the internal/external audits, and investigation results including complaints, proficiency testing results, CAPA, evaluation of the laboratory activities and KPIs, document review, change of policy, the effectiveness of previous CAPA, changes, recommendations, and staff training. The MR was carried out at least once per year. The MR report for 30 November 2022 was discussed. The attendees including their signatures and timing were available.

Proficiency testing schemes

The procedure for proficiency testing was prepared to assess the competency of the laboratory. The procedure was applicable to medicines, psychotropic substances, narcotics and related starting materials except medical devices and cigarettes. The procedure identified test parameters and respective test methods that will be used for proficiency testing. The test methods include HPLC, UV-VIS, dissolution, optical rotation, pH meter, water content by KF, loss on drying, and disintegration (however there was no mention of FTIR, GC, melting point, sulfated ash, conductivity, TOC, TLC, Potentiometric titration).

Validation master plan

The first version of the validation master plan was discussed. This was prepared based on WHO TRS 1019, Annex-3. The areas covered as part of the VMP included equipment qualification, facility qualification, validation/verification of analytical methods, computer system validation etc. The VMP activity was executed using plans and specific SOPs. The SOPs provided the frequency for requalification.

The SOP for the cleaning and maintenance of the laboratory area was available including the checklist for cleaning and maintenance of lab areas. The cleaning and maintenance activity was carried out daily using a checklist. The master schedule for equipment, analytical methods, facility etc. was in place. The laboratory should consider including analyst qualifications.

Internal Audit

Internal audits were performed annually in accordance with SOP. The list of topics to be inspected was the same as listed in the WHO GPPQCL. Auditors were classified in terms of training and experience into four levels: trainee, junior, senior and lead auditor. The audit reports from August 2022 and October 2021 were reviewed and found to be generally satisfactory. The CAPA (Corrective and preventative actions) were listed, tracked, and closed out in the required timelines.

The deficiencies noted from the quality management system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

3. Control of documentation

Document Control was managed through an SOP. The procedure covered aspects such as drafting, storing, superseding and disposal of SOPs, master documents, quality manual and forms. All documents were kept as hard copies and soft copies. Obsolete original hard copies were destroyed by a paper shredder. Forms were issued by QA and logged into the Form Request Logbook. Storage of data on computers was backed-up every two months. Documents generated by the Medicines and Pharmaceutical Starting Materials Sub-Division were controlled using unique headers and footers that contained document numbers including version numbers, page numbers and issue dates. The document warehouse was inspected, and records were archived for 5 years in accordance with national requirements.

The deficiencies noted from the control of documentation section have been addressed satisfactorily and the same will be verified during future PQ inspections.

4. Records

Testing records were generated by the analyst and reviewed for completeness and accuracy by the verifier, Evaluation of Sample Testing Result.

A Logbook dated 22/12/2022, with an index for the preparation of volumetric solutions, was available. Each preparation was traceable to the reagent lot number and expiry date. A unique lot number and expiry date were issued for each newly prepared solution.

The deficiencies noted from the records section have been addressed satisfactorily and the same will be verified during future PQ inspections.

5. Data processing equipment

Some of the Medicines and Pharmaceutical Starting Materials Sub-division instruments were networked to test equipment whereby a number of equipment and instruments were not connected with a server. The procedure controls are implemented, and actions are taken to connect critical equipment with a network-based system.

The procedure for "data management" provided guidance about implementing data management to ensure data obtained are accurate, complete and consistent. The procedure was applicable to all tests.

A separate procedure titled "electronic and quality document data backup" was discussed. The laboratory has identified two administrators who in turn reported to the admin manager. Their main responsibilities were to create new user accounts, reset passwords and deactivate accounts. Backup of the server was automatically done once every day by the IT department whereas backup from the PC client was performed by the lab supervisor once every three months.

The deficiencies noted from the data processing equipment section have been addressed satisfactorily and the same will be verified during future PQ inspections.

6. Personnel

The Medicines and Pharmaceutical Starting Materials Sub-Division had staff with the necessary education, training, technical knowledge, and experience to perform compliance and investigative testing for its customers. This was reviewed during the inspection. Since the last PQT inspection staffing in the laboratory has increased from 21 to 25 with the number of staff in the specific areas listed per activity as follows:

Activity	Number
Head of NQCLDF	1
Technical Manager	1
Head of Medicines and Pharmaceutical Starting Materials Sub-Division, Deputy Technical Manager, Verifier & Analyst	1
QA Manager	1
Deputy QA Manager	1
Administration Manager	1
Head of NAPPZA Sub-Division, Verifier & Analyst	1
Verifier, Analyst and QA Team	1
Verifier & Analyst	1
Analyst and QA Team	4
Analyst	6
IT Team	2
Administration Staff	2
Cleaning Service Support	2
Total number of employees in Medicine and Pharmaceutical Starting Materials Sub-Division	25

The deficiencies noted from the personnel section have been addressed satisfactorily and the same will be verified during future PQ inspections.

7. Premises

The PPPOMN laboratory located on Building I was divided into three floors:

- 1st-floor for the testing of traditional medicines, cosmetics, and administration
- 2nd-floor for the testing of food products
- 3rd-floor for the testing of pharmaceutical products plus GC testing for Cigarettes

The Medicine and Pharmaceutical Starting Materials Sub-Division provides facilities with a suitable size, sufficient space, and reliable infrastructure. These facilities are designed to be suitable for performing their work, to ensure the quality, safety and efficacy of the services provided, and to meet national safety regulations. It was noted that the laboratory has implemented temperature and humidity monitoring using 14 probes for monitoring. Monitoring uses mean kinetic temperature and the average humidity per 24 hours.

The deficiencies noted from the premises section have been addressed satisfactorily and the same will be verified during future PQ inspections.

8. Equipment, instruments and other devices

The Medicines and Pharmaceutical Starting Materials Sub-Division is equipped with instruments and related equipment required for testing, preparation of test items, processing, and analysis of test data. The main equipment used in the laboratory includes liquid chromatography, gas chromatography, dissolution tester, pH meter, balances, disintegration tester, KF titrator, FTIR and UV-visible spectrophotometer, drying oven, and muffle furnace.

The deficiencies noted from the equipment, instruments and devices section have been addressed satisfactorily and the same will be verified during future PQ inspections.

9. Contracts

The laboratory has a procedure for the selection and purchasing of services and supplies. No testing was outsourced as confirmed during the sample management review. When the laboratory was unable to perform the requested test, the sample would be rejected and returned to the requestor. Chemicals and reagents were supplied by. A desktop review on the supplier, dated June 2022, which required the filling of a questionnaire was performed. It was confirmed through documentation that the company did not have a schedule for qualifying suppliers and service providers; however, they completed an evaluation form every time that a service was rendered, or materials or consumables were received. The approved supplier's list indicates the name address and accreditation requirements for each type of qualification/calibration/service.

The deficiencies noted from the contract section have been addressed satisfactorily and the same will be verified during future PQ inspections.

10. Reagents

The laboratory has two separate water systems which were used to produce water of laboratory grade. The water was tested according to the ASTM D1193-91 (Standard Specification for Reagent Water) and classified into Type 1 and Type 2. Type 1 was used for HPLC, GC, mobile phase and AAS testing whereas Type 2 was used for the preparation of dissolution medium. As per the ASTM standard, the water is monitored for resistivity, total organic carbon and temperature. The feed water for Type 2 is tap water whereas Type 2 is the feed water for Type 1. The testing was performed once per year by a vendor which is not justified. During the routine use of the water, the laboratory merely verified temperature, resistivity and TOC from the display. The operational qualification or verification was performed on 16 June 2022 and included tests for resistivity and temperature. The TOC was found on the higher side however, it was not reported by the vendor. The verification report dated 08/08/2022 reported TOC below 50 ppb.

The company indicated that they generally purchased ready-to-use reagents, standards and solutions. There was no justification for the allocation of expiry dates after opening as well as for prepared solutions and mobile phases.

The deficiencies noted from the reagent section have been addressed satisfactorily and the same will be verified during future PQ inspections.

11. Reference substances and reference materials

Reference standards to be stored in cold temperatures were kept in the refrigerator and the freezer because these equipment met the temperature requirements. The reference standards were stored in the freezer between -10°C and -20°C. The mean kinetic temperature (MKT) was calculated for 24-hour readings.

A list of primary reference standards was available. Pharmacopoeia reference substances were checked for validity every two months. This was verified through documentation. Checks were conducted in October and December 2022. Reference standards were checked when received and the quantity was recorded on stock cards. The issued quantity was recorded, and a reconciliation was done after each receipt or issuing.

The deficiencies noted from the reference substances and reference materials section have been addressed satisfactorily and the same will be verified during future PQ inspections.

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

The calibration/qualification/verification instrumentation schedule dated 6 January 2023 was discussed. The calibration was performed by the calibration unit of the PPPOMN and by external parties. The calibration/verification dates were identified in the schedule. The calibration/qualification/verification instrumentation schedule dated 25 March 2022 was reviewed and noted that most of the equipment and instruments were calibrated/verified as per the plan.

The deficiencies noted from the calibration, verification and qualification of equipment and instruments section have been addressed satisfactorily and the same will be verified during future PQ inspections.

13. Traceability

The traceability of the sample from receipt throughout the stages of testing including the analytical test report was available.

The deficiencies noted from the traceability section have been addressed satisfactorily and the same will be verified during future PQ inspections.

14. Incoming samples

The samples were received on the 1st floor. The samples were logged in the register assigning a unique ID before samples were transferred to the 3rd floor. The samples were accompanied by documentation containing details such as the name of the product, batch number, quantity and testing parameters. A billing code is issued by the admin department once it is confirmed that the laboratory has the capability to test certain samples. The sample quantity requested is 3 times the required amount to be used for testing. The SOP described the number of samples required for each test. A checklist was used to record details of the incoming samples including any specific storage conditions. In general, the management of sample receipt was found adequate. Incoming samples were stored in a sample room which was temperature mapped. The mean kinetic temperature (MKT) was calculated for 24-hour readings.

The deficiencies noted from the incoming samples section have been addressed satisfactorily and the same will be verified during future PQ inspections.

15. Analytical worksheet

The analytical reports and certificate of analysis for Rifampicin and Isoniazid tablets were reviewed. The analysis was initiated on 07/01/2022 and completed on 17/01/2022. The testing was performed against the International Pharmacopoeia 2020. The certificate was signed off by the Technical Manager dated 28/01/2022. The test for appearance, identification, weight variation, dissolution, and assay for Lopinavir and Ritonavir was discussed. The analytical worksheet was reviewed and noted that raw data were part of the report.

The deficiencies noted from the analytical worksheet section have been addressed satisfactorily and the same will be verified during future PQ inspections.

16. Validation of analytical procedures

The analytical method validation procedure was discussed. The procedure was applicable to chemical analytical methods (new or changed) that were not derived from compendia. The procedure described the test parameters (accuracy, precision, specificity, detection limit, quantitation limit, linearity, range and robustness) and data elements were validated based on the category (category 1 for testing of APIs in FPPs, category 2 for determination of impurities, category 3 for tests such as dissolution and category 4 for identification test). The analytical method verification procedure was discussed. The pharmacopoeial

methods were required to be verified before use. The test parameters such as specificity/selectivity, precision, linearity, and the limit of quantitation (for impurity) were performed. The verification of the number of analytical methods was performed.

The deficiencies noted from the validation of analytical procedures section have been addressed satisfactorily and the same will be verified during future PQ inspections.

17. Testing

In general, the samples were tested according to the laboratory workplan. Upon receipt of the samples, the laboratory first verified whether they had the capability to perform testing. The International Pharmacopoeia 2020 was used for the analysis of some of the products inspected during the inspection.

The deficiencies noted from the testing section have been addressed satisfactorily and the same will be verified during future PQ inspections.

18. Evaluation of test results

The laboratory had established an SOP on handling out-of-specification (OOS) results which was recently revised to clarify the scope of the procedure. The procedure stated that dissolution and content uniformity tests shall be handled according to respective pharmacopeial procedures. The analyst reported OOS to the supervisor who in turn investigated and further reported to the technical manager. The quality manager was responsible for issuing the QA tracking number. The laboratory has two sections (one for pharmaceutical products testing and another one for testing psychotropic and narcotic substances). The SOP was referenced to UK MHRA guidelines. The investigation was performed in a phased manner following the initial investigation. Hypothesis testing was performed using a protocol. The procedure has referenced 6 related documents (investigation form, testing record, OOS logbook, SOP for CAPA, form for CAPA and hypothesis form).

The deficiencies noted from the evaluation of the test results section have been addressed satisfactorily and the same will be verified during future PQ inspections.

19. Certificate of analysis

Refer to section 15 for more details.

20. Retained samples

The samples were retained for 12 months (if OOS was reported) otherwise stored for 6 months before they were discarded. Retained samples were stored with samples awaiting testing in the sample store. Temperature was controlled and continuously monitored. Temperature mapping was performed as indicated by the laboratory.

The deficiencies noted from the retained samples section have been addressed satisfactorily and the same will be verified during future PQ inspections.

21. Safety

In general, safety instructions including poster displays were provided for the staff members for the safe handling of chemicals, reagents etc. Also, an eye washer and shower facility were available inside the laboratory.

Part 3	Conclusion – Inspection outcome

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, ***National Quality Control Laboratory for Food and Drugs***, located at ***Jalan Percetakan Negara No. 23, Jakarta Pusat, 10560, Indonesia*** was 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 manufacturer, 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 5	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 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 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

4. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4. ***Short name: WHO TRS No. 937, Annex 4***
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

5. 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

6. 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

7. WHO Guidelines for preparing a laboratory information file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 2011), Annex 13. ***Short name: WHO TRS 961, Annex 13***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesPreparingLaboratoryInformationFileTRS961Annex13.pdf?ua=1TRS%20961:%20Annex%2013:%20WHO%20guidelines%20for%20preparing%20a%20laboratory%20information%20file

8. Stability testing of active pharmaceutical ingredients and finished 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 10. ***Short name: WHO TRS No. 1010, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

9. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. ***Short name: WHO TRS No. 1025, Annex 4***
https://www.who.int/publications-detail/978-92-4-000182-4

10. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3. ***Short name: WHO TRS 1033, Annex 3***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

11. 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 1033, Annex 4***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations