World Health Organization

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

Prequalification of Medicines Programme
WHO PUBLIC INSPECTION REPORT (WHOPIR)
Quality Control Laboratory

Part 1: General information

<table>
<tr><td>Name of QC Laboratory</td><td>Centro Nacional de Control de Calidad/ National Center for Quality Control (CNCC)</td></tr>
<tr><td>Physical address</td><td>Av. Defensores del Morro N° 2268, Chorrillos, Lima 09, Perú</td></tr>
<tr><td>Date of inspection</td><td>7-9 August 2013</td></tr>
<tr><td>Type of inspection</td><td>Routine</td></tr>
<tr><td>Type(s) of testing included in the inspection</td><td>Physical, chemical, microbiological testing</td></tr>
<tr><td>Summary of the testing activities performed by the QC Laboratory</td><td>
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<tr><td>Type of analysis</td><td>Finished products</td><td>Active pharmaceutical ingredients</td></tr>
<tr><td>Physical/Chemical analysis</td><td>pH, water content, loss on drying, melting point, viscosity, density/specific gravity, optical rotation, conductivity, residue on ignition, weight, volume, particles in injections, friability, tablet hardness, dimensions, disintegration, dissolution, uniformity of dosage units</td><td>pH, water content, loss on drying, melting point, viscosity, density/specific gravity, optical rotation, conductivity, residue on ignition, weight, volume, particles in injections</td></tr>
<tr><td>Identification</td><td>HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, spectrophotometry (UV-VIS, IR, fluorescence and atomic absorption)</td><td>HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, spectrophotometry (UV-VIS, IR, fluorescence and atomic absorption)</td></tr>
<tr><td>Assay, impurities and related substances</td><td>HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, spectrophotometry (UV-VIS, IR, fluorescence and atomic absorption), volumetric titrations, gravimetric analysis, residual solvents, potentiometry, total</td><td>HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, spectrophotometry (UV-VIS, IR, fluorescence and atomic absorption), volumetric titrations, gravimetric analysis, residual solvents, potentiometry, total</td></tr>
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Contact: prequalinspection@who.int

	organic carbon	organic carbon
Microbiological tests	Sterility test, microbiological tests of non-sterile products (microbial enumeration test and test for specified microorganisms), disinfectant efficacy of preservatives, test for pyrogens, bacterial endotoxins test (LAL), microbial assay of antibiotics	Sterility test, microbiological tests of non-sterile products (microbial enumeration test and test for specified microorganisms), test for pyrogens, bacterial endotoxins test (LAL), microbial assay of antibiotics

Part 2: Summary

General information about the company and site

The Centro Nacional de Control de Calidad/ National Center for Quality Control (hereafter referred to as CNCC) is an agency of the Peru National Institute of Health (INS) that has the goal of performing quality control of medicines, natural products, food supplements and sweeteners, biological products and consumables for human and veterinary use, therapeutic devices, medico-surgical materials, diagnostic reagents, cosmetics and pesticides for domestic use, both of domestic manufacture and imported.

Most of the analyses performed by the laboratory were subcontracted by the regulatory authority (Direccion General de Medicamentos, Insumos y Drogas) as part of their market surveillance efforts.

The CNCC presides over the Network of Drug Quality Control Laboratories in the Health Sector according to what was established since 1992 in the Directive for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products and Related Articles of the General Health Law. CNCC is responsible for authorizing national or private laboratories that seek to participate in this network, through on-site verification of the technical competence of the applicant laboratory.

The laboratory participated in Proficiency testing with PAHO and the EDQM.

History of WHO and/or regulatory agency inspections

The CNCC expressed its interest in prequalification in October 2009 and the first inspection was performed by WHO inspection team within the Prequalification procedure on 25-26 March 2010. This was second inspection performed by WHO inspection team.

The CNCC was audited and accredited by the Assured Calibration and Laboratory Accreditation Select Services (ACLASS) according to ISO/IEC 17025:2005 for the following tests - HPLC, UV-Vis Spectrophotometry, pH measurement, density/specific gravity, weight measurement, volume, dissolution, uniformity of dosage units, sterility, bacterial endotoxins by the gel-clot method or Limulus Amebocyte Lysate (LAL), microbial limits – plate methods, antibiotic potency – cylinder plate method. The last audit was in September 2012. A follow up audit had been planned for September 2013.

Inspected Areas

The inspection covered the following sections of the WHO good practices for pharmaceutical quality control laboratories (GPPQCL) text:

- Organization and management
- Quality management system
- Control of documentation
- Records
- Data-processing equipment
- Personnel
- Premises
- Equipment, instruments and other devices

- Contract
- Reagents
- Reference substances and reference materials
- Calibration, verification of performance and qualification of equipment, instruments and other devices
- Traceability
- Incoming samples
- Analytical worksheet
- Validation of analytical procedures
- Testing
- Evaluation of test results
- Certificate of analysis
- Retained samples
- Safety

2.1. Organization and management

CNCC was legally authorized to perform the tests mentioned in above. The CNCC had managerial and technical personnel with the authority and resources needed to carry out their duties. The organization and management structure of the laboratory was defined. However, the organization chart did not include a listing of the names of the staff occupying key positions.

2.2. Quality management system

The CNCC implemented a quality management system (QMS) based on the following standards:

- WHO Good Practices for Pharmaceutical Control Laboratories
- ISO/IEC 17025:2005 general requirements for the competence of testing and calibration laboratories, for which the laboratory was accredited for more than 90% of its testing activities (last inspection 16-18 July 2012).

In addition, the requirements of the ISO 9001:2008 were also applied, as well as the requirements of ISO Guide 43 (due to activity as organizers of inter-laboratory assays). The QMS was well documented and policies, procedures, instructions, plans, programmes and records were written in detail.

The QMS was defined in a complete Quality Manual, available to all staff, which contained the Quality Policy. Staff was interviewed about their knowledge of the QMS and mission, vision and quality objectives of the CNCC.

Quality objectives were established every year and performance indicators were evaluated monthly and during Management review.

The roles and responsibilities of the different positions were described in the Manual of Functions.

Each member of staff had to sign a confidentiality statement and a declaration of impartiality and independence, every year.
QMS was considered to be generally acceptable.

Customer service: A satisfaction survey was sent to the clients every 6 months by using a template. In addition suggestions and opinions were collected from the suggestions box and evaluated every 3 months.

Complaints
Complaints from external clients and from internal staff were collected and documented. The SOP on complaints was presented. Director General, Executive Directors and secretary of Director General and coordinators were responsible for review of complaints. Corrective/preventive actions (CAPAs) were applied whenever necessary and they were appropriately documented.

Complaints were trended as per total number of complaints, number of complaints per months and nature of complaint. All complaints were received from external clients.

Internal audits: Internal audits were properly planned, executed, documented and followed up according to the SOP. This SOP was also applicable to the external audits (contract laboratories) performed by the laboratory. Internal auditors were trained and qualified, and they were independent from the audited areas.

Audits were carried out using a checklist. Audit observations were listed and CAPAs were given by the supervisor of each area. After audit report was drawn up and given to the Director General, Executive directors and Head Quality assurance. Quality assurance evaluated the report, which was also discussed during management review. The internal audit report from 2012 was shown to the inspectors. It was an extensive document listing a number of observations.

Non-conforming (NC) work/Corrective and preventive actions (CAPA):
CAPAs were managed according to the SOP. In each section there was a logbook to document detected NC. The coordinator of each section recorded the NC and the QA unit verified it and made the follow up of the CAPA. The same form was used to record NC of any origin (routine work, audits, equipment breakdown, Management review, etc). A detailed follow up was made of the CAPA applied and their efficiency was verified and documented.

The corrective and preventive actions from the last inspection were reviewed. Reports were available for each observation, detailing the different actions and their dates. Overall, there were no changes since the last inspection regarding NC and CAPAs.

Management review: Review of the QMS was performed every 3 months according to the SOP and according to the program established for the year. The management review reports were documented in specific forms. Whenever necessary, corrective/preventive actions were identified, which were followed up though the general system. The last meetings that took place in 2013 were on 25 February 2013 and 28 May 2013. The next one was scheduled in August 2013. Their reports were reviewed.

2.3. Control of documentation
A master list of updated QMS documents was available to all staff. Procedures and manuals were reviewed every 2 years, while instructions were reviewed when necessary. All revisions

were properly traceable in an Excel table. Changes were traceable in the document itself by underlining the new/modified text. Forms (templates) were uniquely codified and reviewed independently from the procedures/instructions.

Availability of QMS documents was ensured through documented distribution of controlled paper copies and accessibility by all staff to the electronic (read-only) version placed in the server. Retrieval of obsolete copies was documented and obsolete originals were placed in a separate paper folder and electronic folder.

Staff were notified of the document updates by e-mail, before they received the controlled paper copy. A presentation was made to staff to explain the changes and if necessary further training was organized and documented.

External documents (norms, pharmacopoeias, laws, etc.) were regularly surveyed and the impact of changes in internal documents was evaluated.

Change controls
The SOP on document control was reviewed. It included a section on change control of documents. Among other elements, it stated that obsolete documents should be archived and adequately identified to avoid their involuntary use.

2.4.Records
Records were properly managed according to the SOP. A list of records used in each area was available, which included laboratory logbooks. A compiled list of SOPs was available at the QA unit. Retention times of records were defined according to national law or laboratory needs.

Testing records were properly kept, indexed and compiled with page numbering. Quality Assurance records were properly archived as well in folders (internal audits, non-conforming work, corrective actions, complaints, etc), accessible only to staff of the Quality Assurance Unit.

The records management system SIGEL was implemented after the last WHO inspection.

2.5.Data-processing equipment
The back-up of documents was performed in accordance with the SOP. Back-up of electronic data was done on a monthly basis. Only recently (just prior to the inspection) was the backup done on portable drives. Computers and software associated with HPLC systems were inspected.

2.6.Personnel
A list of signatures/names/functions of all staff was available. An induction programme was prepared for each new member of staff, including general part, about the QMS system and specific technical qualification according to the work area. A training plan was prepared at INS level and a more specific one at CNCC level.

The overall plan for verification of quality of results was available for 2012. The file of a recently hired analyst was reviewed. Her qualifications and trainings followed at CNCC were acceptably documented.

The training given on Microbiology testing was reviewed and found to be adequate.

The reports for competency testing for density and UV-visible performed in 3 July, 2012 were reviewed as well. Variation relative to expected results, variation coefficient percentage and graphical trending was performed for 13 analysts. The manner in which this was handled was found to be acceptable overall.

In general the training, skills, experience, qualification of staff were adequate and well documented.

2.7.Premises

The laboratory premises were considered to be acceptable in size and suitable for storage and performing of the analyses. Temperature was routinely controlled and recorded in the different areas of both sectors. Premises were kept clean and tidy to ensure safe work.

The microbiology laboratory was spread on 2 floors. On the first floor, microbial enumeration was performed and 3 autoclaves were available for sterilization of media, clothing and glassware, and 1 autoclave for sample destruction. It was stated that sterility tests were performed in a Class A Biosafety cabinet, surrounded by the Class B room.

2.8.Equipment, instruments and other devices

Equipment, instruments and other devices were designed, adapted, located, calibrated, qualified, verified and maintained as required by the operations carried out in both sectors (chemical and microbiological).

Instrument verification dated 3 July 2013, was reviewed for the specific FTIR. This was performed using a polystyrene test at 5 different NIST wavelengths as well as signal to noise, background, interferogram and wavenumber.

2.9.Contracts

A network of 3 laboratories was subcontracted to perform analyses for the CNCC laboratory. Contract laboratories were audited annually. A specific contact laboratory audit report and related CAPAs were seen. Audits were carried out using different check lists. The audit plan for 2013 was also reviewed.

Contract laboratories that were part of the network that were supervised and authorized by their laboratory were used for the subcontracting of tests.

2.10. Reagents

Purchases

Procedure dealing with purchases was written in accordance with the National law on purchases. A list of needed materials/services was prepared every year by CNCC. The purchases were managed using the software SIGA-HL. Purchase requests were reviewed and

approved by the director. Delivered reagents were verified at reception and brought to the warehouse of Peru National Institute of Health, after which they were picked up and checked against specifications by the requesting laboratory. All verifications/checks were properly documented.

Evaluation of suppliers of materials and services was properly done according to the SOP. A list of approved suppliers was available was reviewed and was considered to be appropriately maintained.

Additional suppliers of services concerning CNCC could be considered in the process of evaluation (or verify that they are properly evaluated by Peru National Institute of Health), such as external company for waste disposal, company providing security guards and alarms, company for maintenance and refilling of fire extinguishers, etc.

Reagents
Reagents were stored in a safe place (restricted access) under controlled conditions. Reagents were not subdivided. The inventory of reagents was maintained in a Excel spread sheet showing the code of the material, name of the material, storage conditions, grade, location, packaging, lot number, classification (organic, non-organic), safety, manufacturer, expiry date, status (in stock/out of stock), supplier, order number, quantity in stock, date of receiving. Date of the opening and quantity used was recorded on individual packs/containers and on the label.

A rejection policy was deemed not necessary by the laboratory: there was a general/central store in the Peru National Institute of Health that managed the reagents stocks and supplied them to the laboratory following internal orders called PECOSAS. These supplies had been accepted first by this store and in addition by the physical-chemical area at receipt. Receipt and ex stock delivery of glassware, chromatographic columns, other supplies and daily consumption of reagents was managed through Excel database.

Solvents
The quality standard for commercial solvents was defined depending on the test.

Water
Water was received from the Centre of National Production of Biologics (CNPB). The water quality requirements were defined as purified water. Upon receipt, water was filtered via water purification system; afterwards water was tested according with USP monographs for purified water for total organic carbon (TOC) and conductivity were measured in the first volume filtered. These results were recorded.

In the Microbiology sector, water was used to prepare culture media that were sterilized in the autoclave. Water was sourced internally by a distiller.

Reagent solutions prepared in the laboratory
Solutions were prepared in accordance with SOP. The corresponding information was recorded in the analyst's workbook. The information provided on the labels of reagents

(commercial), reagents solutions (in house) and volumetric solutions (in house) included the information required.

Culture Media
In the Microbiology sector dehydrated culture media were used to prepare culture media ready to use. There was a specific area for culture media preparation. This area was well defined and separated. Dehydrated culture media were adequately stored under controlled conditions, according to the supplier information. All culture media were listed and a code number was assigned to each one.

Culture media were prepared following the instructions provided by the supplier according to the SOP "Preparation of culture media". Culture media prepared by the laboratory were clearly labelled.

The quality of each batch of culture medium was controlled by performing the growth promotion test according to harmonization of USP, European Pharmacopoeia and JP. The culture media used were those specified in the harmonization of USP, European Pharmacopoeia and JP.

2.11. Reference materials

SOP for management of reference standards valid for Chemistry and Microbiology sectors was available. Reference standards were stored in safe and controlled conditions. Storage temperature was routinely controlled and recorded twice per day. The central register of reference materials consisted of an Excel file with restricted access and was updated as necessary by the corresponding responsible person. The corresponding reference to the standard used (including batch number) was recorded in the analytical worksheet.

Receipt/storage/distribution and traceability of the reference materials were found to be adequate overall.

Chemistry sector
The validity status of primary (pharmacopoeia) standards was checked before use through on-line access to the information provided by individual Pharmacopoeias.
A specific standard specific lot was inspected along with its records as an example. The date or registration, user, potency were recorded in the SIGEL database system.

Microbiology sector
Microbiological strains were also used as reference materials in order to verify the suitability of the microbiological methods. All the strains were listed. ATCC strains were used. The register for all strains included all the required information. An inventory was maintained and properly updated. The strains were adequately stored under safe and controlled conditions.

According to the procedure for use of strains, micro-organism suspensions were prepared to be used in the microbiological tests. According to the harmonization of USP, Ph. Eur. and JP, no more than five passages from the original master seed-lot were performed. Microorganism suspensions were properly labelled and stored under safe and controlled conditions.

There was a person in charge of the store of strains and microorganisms suspensions.

Whenever a reference material was used, the corresponding identification number was quoted on the analytical worksheet.

2.12. Calibration, validation and verification of equipment, instruments and other devices

There was a specific unit in charge of these activities: Calibration/Metrology. This unit was responsible for the maintenance of the standard weights as well as for the safekeeping of the corresponding instrument documentation, calibration certificates and verification records. In the Metrology unit there was the compiled full list of equipment for both sectors and plan for calibration and verification. Then each sector had a list of its equipment.

The corresponding updated records were available. There was a general programme for the maintenance, validation and calibration of equipment and reference materials. Maintenance and verification of equipment was performed following the SOP.

Calibrations were outsourced either to the Laboratorio de Referencia Nacional INDECOPI or to an accredited laboratory and, whenever possible, calibrations were done internally by the Metrology unit of CNCC.

Chemistry sector

All the equipment, instrument and other devices used for testing were verified and calibrated following the corresponding plans and SOPs.

The calibration/verification status was clearly visible on the corresponding labels.

When an equipment, instrument etc. had been out of the direct control of the laboratory for a certain period of time, according to the procedure Equipment Installation and Operation Control, the re-qualification was considered based on the information provided by the technician.

Volumetric material was calibrated systematically at receipt by Metrology unit following specific SOPs.

Microbiology sector

All the equipment, instrument and other devices used for testing were verified and calibrated following the corresponding plans and SOPs. All calibrations/ verifications were properly recorded. Records for calibrations/verifications included all the required information.

The calibration/verification status was clearly visible on the corresponding labels.

Temperature of incubators, fridges and freezers was monitored by calibrated devices. Theses temperatures were recorded twice per day on a control chart.

2.13. Traceability

The reference material(s), equipment(s), reagent(s), culture media, analyst(s), calculation(s) were suitably recorded in the analytical report and therefore traceability was deemed suitable and sufficient.

2.14. Incoming samples

Sampling

The laboratory was not responsible for sampling for market surveillance. Samples were received from Regulatory Agency. In some cases laboratory performed sampling, for example: upon the request of the Ministry of Health of the products for used in the hospitals or direct request from the manufacturers.

The corresponding sampling plan, including sample size defined in accordance to tests prescribed, was defined. All the relevant data related to sampling were recorded in accordance to the corresponding SOP.

Incoming samples were verified to be large enough to enable replicate analysis as well as to retain samples. Incoming samples were accompanied by the corresponding test request containing all the required information. Incoming samples together with the corresponding test requests were recorded covering all the required information and visually inspected by laboratory staff to ensure conformity of labelling with the information contained in the test request. Incoming samples were marked with the corresponding number of entry in the register. Samples (including retained samples) were stored in safe places under controlled (temperature) conditions in each laboratory (chemistry and microbiology). The corresponding person responsible for forwarding to testing was assigned

Each sector (chemistry and microbiology) received its own samples. Therefore a test request was provided for each laboratory together with the corresponding sample. Samples for chemistry and microbiology were handled separately.

2.15. Analytical worksheet

Analytical workbooks were filled-in in accordance with SOP. It was ensured that a separate worksheet was used for each sample. All the analytical worksheets related to the same sample were assembled together.

The analytical worksheet provided all the required information. All the values obtained from each test, including blank results, were entered on the analytical worksheet. All the graphical results were annexed.

The calculations were made using protected Excel datasheets. The corresponding procedure to validate, verify and maintain Excel datasheets was available.

Analyst notebooks were found to be in good order.

2.16. Validation of analytical procedures

Method verification SOP was reviewed. It covered any test performed by the laboratory. The limits were specified for precision, specificity, accuracy, limit of detection and quantification.

2.17. Testing

The process from receipt of the test request to analysis was examined. An evaluation was electronically recorded in the SIGEL system and includes an evaluation of the completeness of the information, availability of the reagents, equipment, etc. Once this done, a service order was issued and was seen by the supervisor and analyst in the laboratory. An email was sent to the analyst to whom the work was assigned to and the specifications and test methods were available to analyst through the SIGEL system.

The laboratory subcontracted some tests in case of need according to the SOP to authorized laboratories, which belonged to the National Network of Drug Quality Control Laboratories in the Health Sector. These laboratories had been evaluated by INS/CNCC as fulfilling the QMS requirements and were included in the list of approved subcontractors. The laboratories from the Network could subcontract CNCC as well. Results obtained though subcontracted tests were clearly indicated in the Final report.

The laboratory was responsible for coordinating and organizing proficiency testing studies in order to demonstrate technical competence of its own and of the laboratories of the Network The test report was sent to General Directorate and the summary was sent to the participants. As participant, when a satisfactory outcome was received the laboratory did not prepare any formal report. When a non-satisfactory outcome was received, it was treated as a non-conforming work following SOP.

The samples were tested in accordance with the work plan of the laboratory. Test procedures were described in sufficient detail. Any deviation from the test procedure was approved and documented.

Rabbit test for pyrogens

SOP receipt of animals SOP for experiments was seen. Rabbits were received from Centre of National Production of Biologics (CNPB). Afterwards rabbits were maintained at the CNCC pyrogens laboratory. SOP pyrogens test was written in accordance with USP and Ph.Eur monographs. The vivarium where rabbits were maintained was not inspected.

Specifications

The laboratory maintained a specifications archive which included:

- The list of all the pharmacopoeias available in the laboratory (USP, European Pharmacopoeia and British Pharmacopoeia) in their corresponding version in force
- Specifications established by the manufacturers.

Chemistry sector

Test procedures provided sufficient information to perform the test in a reliable manner.

Microbiology sector

Test procedures provided sufficient information to perform the test in a reliable manner and were based on the harmonized monographs for USP, Ph. Eur. and JP.

Verification of the methods was performed. The suitability of the counting method and the sterility test in presence of product was verified according to the corresponding harmonized monograph for USP, Ph. Eur. and JP.

2.18 Evaluation of test results

Two sample determinations were performed for HPLC analyses and correlation was calculated between the average and the appropriate limit (% RSD) as acceptance criteria. See previous WHO inspection report for more details.

Investigation of out-of-specification results (OOS)

Several OOS reports were reviewed for the sequences seen in the computerized system linked to the specific HPLC system. The case of a sample suspected to be a counterfeit was reviewed. The electronic data and investigation forms were seen.

When a doubtful result (suspected out-of-specification result) was identified in the Chemistry sector, a careful review of the different procedures applied during the testing process was undertaken by the supervisor with the analyst or technician following SOP. It had been revised compared to the last inspection by including more detailed instructions for OOS investigation process.

Uncertainty of measurements was covered in a separate SOP.

The OOS register was maintained in an Excel spread sheet. It was verified for 2012. The OOSs for 2013 listed in the register were compared to the samples seen in the sample storage room.

In the Microbiology sector test results were reviewed to determine if they meet the specifications required. When a doubtful result (suspected out-of-specification result) was identified an investigation was performed according to the SOP

Analytical reports

The laboratory issued analytical test reports based on the analytical worksheet. Any amendments to the original analytical test report were issued as a new corrected document.

The reports for sterile samples were required to be issued in 25 working days from receipt. The reports for all other samples were required to be issued in 15 working days from receipt. In both cases the laboratory was requested to indicate which of them were “conform” (met the specifications).

2.19 Certificate of analysis

Test results were electronically entered and recorded in the SIGEL system. Analyst results were reviewed and compared to the limits of the method in the appropriate pharmacopoeial reference or method. The approval by the supervisor and coordinator was recorded for each and every test in the electronic system. Once everything was approved, a draft of the entire certificate of analysis was generated. The draft was either approved or rejected by the supervisor. Once approved by the coordinator, the final certificate of analysis was generated in PDF.

2.20 Retained samples

Retained samples were kept in cardboard boxes in the same area as samples awaiting testing.

2.21 Safety

Safety manual was available to all staff. Equipment for individual protection and safety instructions were available as well as poster displays on the walls and on laboratory doors. Fire extinguishers were periodically revised and refilled and were accessible in all areas of the CNCC. First aid materials were available at the reception desk. All staff were trained on first aid measures and use of fire extinguishers, as well as on risks linked to the use of reagents and disposal of waste.

The adequate function of fume hoods was verified annually. Safety showers were available. MSDS sheets were also available to all staff.

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 ***Centro Nacional de Control de Calidad / National Center for Quality Control (CNCC)*** was considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories for the scope activities listed below:

- Physical/Chemical and microbiological analysis of finished pharmaceutical products and active pharmaceutical ingredients.

All the non-compliances observed during the inspection that were listed in the full report 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.