Prequalification Team
WHO PUBLIC INSPECTION REPORT
Quality Control Laboratory

Part 1: General information

Name of the QC Laboratory	INFARMED I.P. Quality Control Division (DCQ)
Physical address	Av. Brasil No. 53, Edifício Tomé Pires, 1749-004 Lisboa, Portugal
Date of inspection	16 -17 July 2015
Type of inspection	Routine inspection
Type(s) of testing included in the inspection	Chemical, Physical, Microbiological
Summary of the testing activities performed by the QC Laboratory	

Type of analysis	*Finished products*	*Active pharmaceutical ingredients*
Physical/Chemical analysis	pH, density, optical rotation, osmolarity, limit tests, degree of coloration of liquids, clarity and degree of opalescence of liquids, loss on drying, water content, residual solvents, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content)	pH, optical rotation, melting point, loss on drying, osmolarity, limit tests, sulphated ash, degree of coloration of liquids, clarity and degree of opalescence of liquids, loss on drying, water content, residual solvents
Identification	HPLC (UV-VIS, DAD, fluorescence, RI, ELSD, MS), GC (FID, MS), TLC, UV-VIS spectrophotometry, FTIR, Chemical identification tests	HPLC (UV-VIS, DAD, fluorescence, RI, ELSD, MS), GC (FID, MS), TLC, UV-VIS spectrophotometry, FTIR, Chemical identification tests

	Assay, impurities and related substances	HPLC (UV-VIS, DAD, fluorescence, RI, ELSD, MS), GC (FID, MS), TLC, UV-VIS spectrophotometry, potentiometry, volumetric titrations, FTIR	HPLC (UV-VIS, DAD, fluorescence, RI, ELSD, MS), GC (FID, MS), TLC, UV-VIS spectrophotometry, potentiometry, volumetric titrations, water content, residual solvents, FTIR
	Microbiological tests	Sterility test, Total Microbial Counts, Test for Specified Microorganisms, Microbial assay of antibiotics	Sterility test, Total Microbial Counts, Test for Specified Microorganisms, Microbial assay of antibiotics
	Bacterial endotoxin testing	Gel Clot, Kinetic chromogenic	Gel Clot, Kinetic chromogenic

Part 2: Summary

General information about the laboratory and site

INFARMED was established in 1994 under the supervision of the Ministry of Health. It was a public institute with financial and administrative autonomy. Its first mission is to regulate and supervise the sectors of medicines and health products.

The laboratory was responsible for post-market surveillance of 1000 medicines, 20 APIs, 150 health products, including cosmetics and medical devices. They were also responsible for testing samples that were the subject of quality alerts, falsified medicines, and suspicious food supplements. They were also the official control authority for batch release for blood products (OCABR).

INFARMED is among the most active laboratories for testing centrally authorized products for the EMA.

It signed a contract with the UN Development program for the testing of anti-retrovirals, anti-tuberculosis and anti-malarials.

It was prequalified in 2011 by the WHO.

History of WHO and/or regulatory agency inspections

This was the first WHO inspection. The laboratory had received the following audits:
- IPAC (National Accreditation body) 01-02 December 2014
- IPAC 05-06 December 2013
- IPAC 22-23 November 2012
- IPAC 21-22 and 24-25 November 2011
- IPAC 11-12 November 2010
- IPAC 27 and 30 November 2009
- IPAC 13-14 November 2008
- IPAC 19-20 December 2007
- EDQM (European Directorate for the Quality of Medicines & HealthCare) 14-16 February 2012
- EDQM 27-29 February 2008

Focus of the inspection
The inspection focussed on the WHO good practices for pharmaceutical quality control laboratories (GPPQCL).

Inspected Areas
The inspection covered the following sections of the WHO 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 (test report/protocol)
- Retained samples
- Safety

Laboratory information file (LIF)
The LIF was prepared by the laboratory and sent to the inspectors prior to the inspection.

2.1. Organization and management

DCQ has implemented a Quality Management System according to EN ISO/IEC 17025:2005 detailed on the Quality Manual (MQ/04) and in several SOPs in use. DCQ was accredited according to EN ISO/IEC 17025:2005 by the Portuguese National Accreditation Body (IPAC) since 2007.
As part of the European OMCL Network, DCQ has implemented the Network Quality Guidelines, available at http://www.pheur.eu/en/Quality-Management-QM-Guidelines-86.html.

DCQ was divided into two laboratories, the Pharmaceutical Chemistry and Technology Laboratory (LQTF) and the Biology and Microbiology Laboratory (LBM).

The Head of the DCQ direct reported to the Management Board of INFARMED.
The Quality Manager, Head of LQTF and Head of LBM were part of the structure of the DCQ, directly reporting to the Head of the DCQ.

Appropriate document structure was implemented.
Beside the Quality Manual, five levels of documents (e.g. GRL=general SOPs, MA=analytical methods, EQP=equipment SOPs, forms and records) were defined which could be identified directly by the document number.

Management review was done by the Executive Board, the quality managers, and head of laboratories as well as their deputies – review of SOPs was covered during this meeting. The management review procedure dated 20 March 2014, was reviewed. Detailed pre-reports were prepared prior to the meeting and discussed during the meeting. A detailed report was written and signed off by all staff members present after the meeting. Meetings took place once a year.

2.2 Quality system

Internal audits:
The procedure on Internal Audits (Auditorias Internas), dated 4 May 2015, was reviewed. It stated that all activities would be audited once per year. The programme for 2015 was reviewed and included two audits planned for 2015, with one that was already performed on 6, 21, 22, 27 and 28 May 2015. Each audit was done in accordance to a pre-established plan. Each non conformity was addressed through a non-conformity record including a description of the root cause, corrective action, as well as impact assessment. This was found to be acceptable in general.

Out-of-specification (OOS) test results:
The procedure on out-of-specification results, effective since 13 January 2012, was reviewed along with the register for 2015. Detailed forms were filled. The level of documentation was acceptable. When no root cause was found, different extraction methods were verified as hypotheses. Recovery samples were prepared in the case of OOS results to verify whether the extraction method was effective.

Confidence intervals were calculated on 6 test replicate results – these calculations were performed when the result was close to the specification limit (e.g., a result of 94% vs a limit of 95%) – if the confidence interval was not going totally outside of the specification interval, then there is a doubt on the result. The % RSD is taken into consideration into this. Triplicate sample preparation is done by principle. According to the OOS SOP, if part of the confidence interval is within the specification, more careful analysis of the results should be performed and decisions taken on a case-by-case basis.

Deviations
The procedure entitled "non-conforming testing work, non-conformities, complaints, preventive actions and improvement actions" (Registo de Trabalho Nao conforme, Nao conformidades, reclamacoes, accoes, preventivas e de Melhoria), was implemented on 14 July 2015 (but previous versions had been established since 2005).

2.3 Control of documentation

Procedures were tracked using a list that included the dates of all the revisions that took place over the years since the establishment of the quality management system. The date of approval and the date of availability of the SOPs were recorded and were usually the same day. There was no requirement for training on SOPs prior to their implementation but this was done on an informal basis.

All of the staff was notified of the availability of the new procedure by email. Each email had a read-receipt. Each email stated that a new procedure was in place, and that it was stored on the system and that the previous procedure is obsolete and no longer available. All staff members had access online to the pdf file version of the document. If staff printed SOPs, each SOP had a statement that it is only valid for use at the time of print-out.

History of changes was part of every SOP. New text was also highlighted in the new version.

Procedures on documentation retention specified a retention period of 3 years on site and 7 years off site.

2.4. Records

Detailed laboratory notebooks were maintained by each analysts. Each page was numbered, registered and verified. Each laboratory notebook was numbered and attributed according to the procedure entitled "Cadernos de Laboratorio", dated 15 December 2008.

Data was archived on disk and tape and two different off-site locations. The laboratory was requested to restore data from 2012 as a demonstration.

Back-ups were defined in the procedure for IT entitled "Procedimentos Operacionais de tecnologias de informacao" and archiving in the SOP entitled "Envio tapes para custodia". New tapes are made every week and sealed to ensure that they have not been tampered with. They are delivered to an external entity called ASCS. The SOPs did not specify how data would be destroyed and the oral accounts from IT representatives stated that they would be destroyed after 6 months or 1 year. This was resolved in CAPAs.

2.5. Data-processing equipment

Calculations were performed using Excel Spreadsheets which were saved and readily retrievable as blank forms only since the completed forms were not saved, but the printed forms were kept as records of the calculation.
Electronic calculation forms were validated. Validation was documented and included the formulas that were usually hidden from the templates. In the example of the form used to calculate confidence intervals, the forms ability to produce the correct statement that it was inside or outside the confidence interval, was tested. The worst case example was “doubtful” test results (results that were close to specification limits).

2.6. Personnel

There were 33 staff members in total, including thirteen analysts in the chemical laboratory and five analysts in the microbiological laboratory. Staff was not trained in sampling as colleagues from the inspectorate were responsible for sampling.

Qualification matrixes were established and updated for each member of personnel working in the laboratories. Details included whether the staff member was able to execute the test, validate it, verify the data, or is able to prepare all materials for the test.

DMR, EJC, IV, MCF were not qualified to check dissolution test data according to the chart, but were qualified to execute the test.

Everyone who was able to perform a test was allowed to perform equipment qualification. Laboratory management assumed that anyone that is able to operate a piece of equipment should be able to perform preventive maintenance on the equipment. This would include, gradient, flow, linearity, changing of the lamp, changing pump parts, remove the clog – this is a common transversal approach. For HPLC there is nevertheless external maintenance but qualification after the maintenance is performed in-house. After this qualification, there is a requirement for requalification after 12 months, with a maximum limit of 15 months. External maintenance is performed every 2 years for HPLCs. Internal maintenance is performed in-use according to need (when signs of overuse are appearing, for instance, when high pressure is obtained without use of mobile phase containing salts, is a trigger for changing pump components), as well as after the external maintenance. Staff was trained by suppliers of the equipment and the knowledge was shared amongst the staff members.

Analyst qualification was covered by the SOP entitled “Minimum requirements for handling the competence and qualification of personnel” (Requisitos minimos de manutencao da competencia e qualificacao de pessoal), dated 25 November 2014, which required comparing the results between analysts but for non-quantitative methods only. Detailed comparative testing reports were maintained, as seen in the example for 3 analysts for TLC. For quantitative methods such as assay using HPLC, the analyst was requested to perform method validation independently of the active substance. If validation criteria was met, more than 90% of the time over the year, the analyst continued to be qualified (maintenance of qualification). The SOP did not specify quantitative criteria for qualification of new analysts, but in practice, verification of the ability to validate (specificity, R2, Error, precision, repeatability, spiked sample testing within acceptance criteria) for each of the quantitative methods was performed.

There were 3 analysts, according to the qualification matrix, who were qualified to do GC (initials of NGS, RP, SV). This was verified on GC instruments in the laboratory.

2.7. Premises

Premises were generally suitable for the activities conducted and were very well maintained. All of the necessary space was available with appropriate segregation.

Microbiological laboratory was part of the separate laboratory area of the LIB.
Appropriate areas for Sterility test, Total Microbial Counts, Test for Specified Microorganisms, Microbial assay of antibiotics, and where growth media were prepared
Two isolators were installed for sterility testing.
Area for microbiological testing of non-sterile products was equipped with two Laminar air flow cabinets (grade A classification). Surrounding area of the safety cabinets was not classified but HEPA filtered air was provided and the room was held in overpressure to the other areas. Building management system was in place.

2.8 Equipment, instruments and other devices

Physicochemical testing

- **High performance liquid chromatography (HPLC):** A large number of HPLC systems were available at the laboratory and were equipped with Empower. These were in good condition and well maintained. The only issues noted pertained to the protection of electronic data, software settings and user access rights. See “Part 5” for observations.

- **Infrared spectroscopy:** FTIR and FITR/NIR were in use at the laboratory. The FTIR was a Bruker Equinox 55 model. Not all analyses were registered in the equipment logbook (e.g., cefazoline was tested but was missing from the logbook.). This issue was resolved in CAPAs.

- **GC:** GC-FID and GC-MS equipment was available at the laboratory. The GC-MS was operated using Enhanced ChemStation E.02.02.1431 software. All four systems had “out of service” status because they were rarely used and would be “re-calibrated” when required before next use.

- **UV-Visible spectrophotometry:** one UV/VIS spectrophotometer was seen.

- **Dissolution testing apparatus**: three dissolution testers were out of use but three others were available and in adequate working function.

- **Analytical balances:** there were thirteen analytical balances available (one out of use) when counting those available in biology/microbiology, with 2 precision balances that could weight down to 3 mg. The balance readings were recorded either in the laboratory notebooks or the analytical worksheets.
Logbooks containing the information about the usage of the balances were available.

- **Other testing equipment:** Polarimetry, potentiometric titration equipment
One polarimeter (POLAAR 35, Optical Activity Ltd) was available.

Several Titrators (METROHM) were installed (e.g. moisture determination with Karl Fischer titration, potentiometric titrations)

Biological and microbiological testing

- **Bacterial endotoxin testing**

Testing was done with Gel-clot or Kinetic chromogenic method.
For kinetic chromogenic method ELx808™ Absorbance Microplate Reader (internal number LEITOR MCP 3) was used. Temperature mapping was done (37±1°C).
During the tour through the laboratory at the first inspection day, logbook for usage of the equipment was not complete. This issue was resolved in CAPAs.
Explanation and documentation was provided by DCQ at the second inspection day. According to this, last analysis was done on 08 July 2015. But this analysis was not valid because of problems with the microplate reader. Exchange of light source will be necessary.
For this reason, the test was repeated with the Gel-clot method.

- **Autoclaves, Incubators**

Two horizontal autoclaves and several incubators were installed.
Temperature mapping was done once a year with external contractor. Calibration labels were fixed at the equipment. Printouts from the autoclave were filed to document the sterilisation cycle.

- **Microbial Assay of Antibiotics – Diffusion method**

The necessary equipment and the execution of the method were demonstrated.
Camera system (digital microscope DMLS IV/01) with software LEICA QWin (modular image processing and analysis software package) was used.
Quantitative Assay was done on square plates (24x24 cm) with 36 inhibition holes each.

- **Tests for sterility and Microbial Examination of Non-Sterile products**

See 2.7, 2.12

2.9 Contracts

Contract testing was not performed. Only repairs and specific types of calibration was contracted out for specialized equipment such as HPLCs and dissolution testing stations.

2.10 Reagents

The procedure on management of reagents and solutions in the laboratory No. LAB-PEG/12/03 was reviewed (entitled “Gestão de reagentes e soluções em laboratórios”).

Purchases

The policy for the purchasing of products and reagents (“Aquisição de productos”), No. GRL/406/01/13, dated 5 May 2015, was reviewed. The analyst was responsible for establishing the requirements for new acquisitions of reagents, consumables, culture media, standards and reference materials as well as volumetric glass. Suppliers were selected from the qualified supplier list. The historical data was used to qualify suppliers and assign a score according to criteria specified in a table in the SOP. For instance, suppliers who did not provide quality certificates for each lot when applicable, were given a rating of 1, with 0 being the desired rating. The points attributed for the

various criteria were summed up, averaged and depending on the score the supplier was added to the qualified supplier list. Materials were not purchased from suppliers that had unsatisfactory results.

Water for laboratory use
Supply, storage and distribution of water was reviewed. Two types of water were used:
Pure water
Four reverse osmosis / EDI units (Millipore ELIX 20 and 70) were installed to generate pure water for regular laboratory applications and instrument feed.
Storage tanks containing UV units were installed together with circulation loops.
System description was available (EQP/117/02, 15 July 2015).
According to the information given by DCQ additional 0.22 µm filter was installed in the distribution loop (PROD-AGUA 3). However, corresponding information was missing in the document.
Water specification and monitoring was described in the applicable SOP.
Sanitisation of the circulation system can be done with chemical agents, when needed. But there was no reason to do this during the last 2 years.
Online measurement of the resistance was installed. Limit was given with ≥ 0.2 MΩ*cm.
Microbiological monitoring showed results below 25 cfu/ml in 2014 and 2015. It was done every 3 months for storage tanks and distribution systems. Alarm limit was set at 70 CFU / ml. Action limits was at 100 CFU/ml.
Filtration method according to the Pharm. Eur. was used for microbiological tests.

Ultrapure Water
The pure water produced as above described was subjected to further purification steps using a combination of ion-exchange, photo-catalytic oxidation and ultrafiltration by several Milli-Q devices (Millipore, stand-alone units connected to the circulation loops from the Pure water system). Limit for resistance was set at ≥ 18 MΩ*cm. This water was also used for chromatography (quality according to Pharm. Eur.).
Microbial monitoring was done every 3 months. Alarm limit was set at 1 CFU/ml. Action limits was at 3 CFU/ml. Results seen were below the limits (mostly below 3 CFU/200 ml).

Reagent solutions prepared in the laboratory
Mobile phases containing buffers had a maximum expiry date of 1 week.

2.11 Reference substances and reference materials
Reference standards were generally provided by marketing authorization holders, as well as by EDQM and USP. Their management was generally acceptable.

2.12 Calibration, verification of performance of and qualification of equipment, instruments and other devices
Equipment qualification
The general SOP about utilisation of equipment was presented (GRL/505/01/09, 14 July 2015).
Methods of qualification were described. A link to the OMCL core document was given.
The setup of the schedule for calibration and preventative maintenance was described.
It stated that problems with the equipment / events should be documented in the logbook available for every equipment in use.

Example:
Reverse osmose unit, PROD-AGUA 3, used in LBM
Installation qualification was documented on 1 Aug 2013.
The certificate from the manufacturer for the equipment was available (Mfg Date: 10 June 2013, Millipore, Catalogue No: ZLXS50020, ELIX 20).
Equipment log was available from the beginning of operation/use.

Examples checked during the tour through the laboratories:

- **Analytical balances:**

Automatic internal adjustments were done and performance verification was performed only once per week.

- **Dissolution equipment:**

Dissolution calibration kit: it was calibrated once a year.

- **Infrared spectroscopy:**

FTIR equipment was qualified once per year and results were compared to those of the reference values for polystyrene.

- **Dissolution testing equipment:**

Qualification was under way for one of the dissolution testing apparatus available at the laboratory.

- **Polarimetry**

Document EQP/109/02 (dated 10 November 2008) contained information about calibration interval of 3 years. In addition, there were annual controls with sucrose solution and daily checks with Quartz Control Plates. Details of performing the analytical method were described in a test procedure dated 01 October 2014.

- **Laminar air flow cabinets (grade A)**

An accredited laboratory, “TradeLabor”, did the last qualification of cabinets in March 2015.
All relevant parameters (e.g. filter integrity, check for laminar airflow, air velocity, particle counting) were checked and found in compliance. Test reports were available.
Microbial monitoring was in place (settle plates during the sample preparation process).
Additional monitoring by air sampling was done every 3 month, at rest conditions, to evaluate the efficiency of air filtration.

- **Isolators used for sterility testing**

Two Positive pressure flexible wall isolators were used for sterility testing.
Overpressure was specified with >50 Pa during processing. Leak test (pressure reduction should be <8 Pa/min) was done every day before starting the sterility testing.
Isolator 1 was used for transfer to Isolator 2 (working isolator) and sanitized with vaporized hydrogen peroxide (VHP) every working day. Working isolator was sanitized once per month.
Qualification of isolators, regular maintenance and monitoring during the process of sanitisation and processing was documented on an appropriate way. Final check for absence of hydrogen peroxide after sanitisation was done with DRÄGER test tubes (limit <3 ppm).
Documentation on sanitisation was available. The specified intervals have been met.

Environmental monitoring was done for the working isolator only.

Microbiological monitoring
Document BBM-PET/28/02 (06 July 2009) was available.
Gloves used during the test procedure were checked for sterility after each analysis.
Additional monitoring of the air inside the isolator was done by liquid impingement method with thioglycolate fluid. There should be no growing in the media used (sterility).
The incubation period was 14 days (32.5°C). Correct limits were given in the SOP.

Particle monitoring
Issues were raised with regards to the action limits for particle monitoring given in the valid SOP (31 October 2011) and were resolved in the CAPAs.

The following example was reviewed during the inspection:
Documentation for the particle monitoring on 02 July 2015:
Results of the online measurement were documented per cubic meter. Several results for 5 µm particles were above 20 particles per m^3 (maximum was 127 particles per m^3 during the material transfer from Isolator 1 to Isolator 2).
Finally, the average of the particle concentration was calculated. The result was 34 particles per m^3 for this isolator run.

2.13. Traceability
Traceability to reference standards, balances and instrument used was generally acceptable from the records reviewed during the inspection.

2.14. Incoming samples
Samples were registered in a database. Numbers were assigned sequentially and labels were printed out.

2.15. Analytical worksheet
The analytical worksheets used were very detailed and generally acceptable.

2.16. Validation of analytical procedures
For related substances, the laboratory verified whether the run time was acceptable since this is not always specified in methods. As part of method verification, test runs were performed and documented in the analyst logbooks for uncommon situations. In the case of this laboratory and as a regulatory authority, such practices are acceptable as the excipient and impurity profile is unknown and would vary from one manufacturer's product to another.

For HPLC methods, method validation was performed for each series of samples (e.g. 5 samples containing rifampicin). If the series is interrupted by a change in column then a calibration curve containing a minimum of 4 concentration points between 80 and 120% is injected at the beginning of the series for determination of linearity. System suitability standards are also injected before and after the curve to demonstrate that the calibration curve is valid. Quantitation of test results is performed with the calibration curve.

For limit tests, for samples, results that are suspected to be out of specification, a test for standard addition that should be higher than 5 times the limit of quantitation was performed in order to confirm that the impurity that is found is really that impurity as means of guaranteeing the identity of that peak.

2.17. Testing

- Microbial Assay of Antibiotics – Diffusion method

There were only two tests in 2015 so far.
Diameter of the zones of inhibition was measured manually with the LEICA computerized system.
Results were documented on the form ImpBBM-178/01 "Microbial assay of antibiotics by diffusion method".
After measurement of all 36 zones, calculation of results was done with software in use.
Data were transferred manually from the form to the software.
Together with the measurement, the recordings of the digital camera system were archived.
Analysts do not know the exact position of standards and samples on the growth medium to avoid influence on the reading of the data.
Review of data was discussed. However, so far there was no need to implement measurement of diameter by a second analyst.

- Test for sterility

Test was demonstrated in detail.
Steritest™ EZ Devices Double-Packed (Merck Millipore) were used.
Details of documentation for internal sample number 20150659 (Ringer solution with lactate, batch 53233) were checked.
Preparation of sterility tests was done on 02 July 2015. Reference numbers of all materials used were documented together with results of microbiological and particle monitoring done in the isolator during preparation.
After incubation of 14 days final evaluation was done on 16 July 2015.

- Microbiological testing of non-sterile products

A Log book was available.1 example was reviewed for internal sample number: 20140211:
Documentation was detailed, including batches of all materials, equipment used, sterilisation cycles and culture media, negative controls, positive controls, validation of recovery of test strains. For validation 5 test strains were used and results were recorded (recovery in between 58 and 117 %).

Concentration of test strains suspensions used for method validation, growth promotion or positive controls was analysed with turbidity measurement (600 nm). Additional measurement with microbiological methods was in place.
Suspensions were stored at temperature below – 80 °C.

2.18. Evaluation of test results

In general, the final results appeared acceptable and were summarized in clear and concise certificates and test reports.

2.19. Certificate of analysis (CoA)

Certificates of analysis ("Boletim de Analise") were issued and signed off by the director of the DCQ. The level of detail included was considered adequate in general.

2.20. Retained samples

Remaining samples, once tested, were not usually kept because according to the local legislation, retention samples should be kept by the marketing authorization holders, which are to be provided upon request. When covered by contracts, samples are kept up to 1 year after the expiry date.

2.21. Safety

Safety eye showers and an appropriate number of chemical fumehoods were available in all laboratory sections.
Biological and microbiological laboratory was classified as biosafety area (BSL 2) with restricted access.

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 the INFARMED I.P., Quality Control Division (DCQ), 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 analysis of finished pharmaceutical products and active pharmaceutical ingredients
- 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.