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

| **Part 1** | **General information** |
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| **Inspected laboratory details** | |
| Name of Laboratory | Drugs Testing Laboratory Faisalabad (DTLF) |
| Address of inspected laboratory site | A block, near DPS School G.M. Abad,<br>Faisalabad, 38000,<br>Pakistan |
| **Inspection details** | |
| Dates of inspection | 23-25 September 2019 |
| Type of inspection | Initial |
| **Introduction** | |

Brief description of testing activities

| Type of analysis | Finished products | API |
|---|---|---|
| Physical/chemical Analysis | pH, water content, loss on drying, friability, tablet hardness, tablet dimensions, uniformity of dosage units (mass, content), disintegration time, dissolution, viscosity, density/specific gravity, | pH, water content, loss on drying, density, melting point, conductivity |
| Identification | IR, TLC, HPLC, UV, spectrophotometry and basic tests | IR, TLC, HPLC, UV, spectrophotometry and basic tests |
| Assay | HPLC (UV-VIS, DAD, RI detection), GC, UV, and FTIR spectrophotometry and volumetric titrations, polarimetry<br>Determination of related substances and impurities by comparison with a reference standard (if available) | HPLC (UV-VIS, DAD, RI detection), GC, UV, and FTIR spectrophotometry and volumetric titrations, polarimetry<br>Determination of related substances and impurities by comparison with a reference standard (if available) |


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| General information about the laboratory | The Drugs Testing Laboratory Punjab Faisalabad (DTLF) is a regulatory laboratory that was established in terms of the provisions of section 15 of Drugs Act 1976 of Pakistan, as part of the Primary & Secondary Healthcare Department Government of the Punjab. It provides analytical services for medicinal products to Drug Control Wing, Government of Punjab, Primary & Secondary Healthcare Department. |
| History | DTLF became operational in July 2015. In 2016 an initiative to modernize systems, facilities and equipment started to be implemented.<br>DTLF was ISO17025 certified by Pakistan National Accreditation Council (PNAC) in July 2018 |
| **Brief report of inspection activities undertaken – Scope and limitations** | |
| Areas inspected | Quality Management System, including Management Review<br>Quality Assurance and complaints<br>Personnel<br>Training and Safety<br>Documentation and Records, including sample processing and OOS handling<br>Premises and Equipment, including calibration<br>Validation – Qualification of computerized systems<br>Validation of analytical methods<br>Evaluation of test results<br>Laboratory Practices<br>Reference standards – Reagents – Water |
| Restrictions | N/A |
| Out of scope | In agreement with DTLF's senior management, the microbiological laboratory was excluded from the scope of this inspection since environmental and microbiological qualification had to be completed. |
| **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 | Non conformity |
| NCA | National control authority |


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| 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** |
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## 1. Organization and management

The laboratory had managerial and technical personnel to oversee the quality management system and procedures for performing tests and/or calibrations, validation and verification, and to initiate corrective actions when required. Roles and responsibilities were specified in signed job descriptions. The Quality Manager had a functional relationship with the Director. Analyst's employment contracts held declarations of no conflict of interest and declaration of confidentiality.

Registries

Registers were kept of CAPAs, OOS, Change Controls, Complaints and Non-Conformances. Data from these registries were input to review documents at different levels.

## 2. Quality management system

The laboratory had established, implemented and maintained a quality management system appropriate to the scope of its activities, and the elements of the quality system were documented. The quality system referred to ISO 17025 and WHO Good Laboratory Control Practices. The laboratory had been certified according to the ISO 17025:2015 by the Pakistan National Accreditation Council (certificate number LAB 159; Issued 24.7.2018, valid till 23.7.2021). The tests included qualitative analysis, identification, assay for active ingredient, uniformity of dosage units (mass variation), sterility, pH. The accredited methods included FTIR, UV visible spectrophotometer, HPLC, Liquid chromatography, Infrared absorption, spectrum UV absorbance. It was noted that GC was not included in the accredited scope of methods. The quality policy was appropriate to the operations of the facility. The quality policy and objectives had been endorsed and were implemented.


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Quality risk management was incorporated in the quality management system. It allowed for identification and evaluation of risks in a structured way.

Quality manual (QM)
DTLF's Quality Manual was briefly reviewed. The manual included the QMS principles of the laboratory and was used to communicate to personnel the laboratory's quality policy and quality objectives, to make personnel familiar with the processes used to achieve compliance with quality requirements.

Confidentiality, independence, conflict of interest
The quality manual adequately described the principles of confidentiality and conflict of interest of personnel.
Newly recruited personnel were required to complete a declaration of conflict of interest at the time they were recruited and upon renewal of their contract. The principles were reinforced through trainings**.**

Organization structure
The organization chart was presented and was also included as part of the QM and LIF. It adequately depicted the organizational and hierarchical structure of the laboratory and the independence of the Quality Manager. It was noted that a number of posts remained vacant.

Change Control
A procedure on change control was established and it described the principles for managing and implementing changes. Changes were reviewed and assessed by the relevant technical personnel and approved by the QMS Manager before implementation of a change. The procedure applied to changes in new and existing procedures, equipment, specifications, test procedures, organogram and job descriptions. Changes approved by the government and Provincial Quality Control Board (PQCB) were outside the scope of this procedure. Changes were categorized into Major and Minor. Impact assessment of the changes was performed by the change control review board. The board was appointed by the QMS Manager. Minor changes were to be closed within 15 working days while major changes were to be closed within 30 working days. A change control register/logbook was in place. The change control forms indicated further categorization of changes into high, medium and low. However, the categorization of changes as high, medium, low was not defined in the procedure for change control. Moreover, impact assessment of changes on other processes was not documented. Appropriate CAPA were implemented following the inspection


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Deviations

A procedure for managing non-conformances was presented. Non-conformances were categorized as minor and major depending on the level of impact on test results. Examples included:

- OOS/OOT
- Environmental factors
- Equipment malfunction
- Customer Complaints/ negative feedback
- Non-conformance identified during management review meetings, internal or external audits.

A procedure on handling deviations was also available. The procedure described how "planned" deviations from official testing methods and from management system procedures were allowed. There seemed to be some overlap on handling of non-conformances and deviations. The procedures were created to comply with terminology used in ISO 17025 and WHO TRS on GLP. There were logbooks for registering non-conformances and deviations. Appropriate CAPA were implemented following the procedure.

Complaints

The laboratory had a procedure for registering, investigating and resolving complaints. A template for reporting complaints was available on the internet but complaints could be received by Email, phone or fax. A logbook for registering complaints was presented. Eleven complaints were registered in 2018 mostly referring to delays in reporting of test results. In 2019, four complaints regarding delays in reporting were logged. The majority of delays were not validated since the test reports are available on a web-application but the complainants were not aware of the application.

Management reviews (MR)

A procedure describing management responsibilities and review meetings was presented. Management reviews were held annually or whenever required. The agenda of the management review meetings was clearly defined in the procedure. The agenda included changes, fulfilment of objectives, suitability of policies and procedures, status of actions from previous management reviews, corrective actions, outcomes of internal audits, assessment by external bodies, changes in the volume and type of work, customer feedback, complaints, results of risk identification. Management review minutes were maintained by the QMS Manager. Management review minutes held on 19.12.2018 and 18.07.2019 were reviewed. The procedure was followed.

Trend analysis

The procedure for trend analysis describing the determination of existing and emerging trends based on data generated by various analytical or support activities was reviewed. According to the procedure trends were to be generated for the following: environmental monitoring, customer feedback, corrective actions, complaints, proficiency testing, equipment verification among others. The trends were reported as part of management review. The trend analysis plan for the year 2018 – 2019 was in place. Trending of complaints (June 2018 to April 2019) was reviewed. 7 complaints had been received. All the complaints had been resolved.


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Internal audits
A procedure for conducting internal audits was in place. Internal audits covered all laboratory activities and consisted of four parts: documented evidence for structure and resources, process and management requirements, laboratory practices, stores and sample room. A Lead auditor was assigned for each self-inspection and his/her qualifications were defined. Annual audit plans were drafted. The 2018 and 2019 annual plans were reviewed. Observations and findings were documented, CAPA were identified and implementation was monitored. Audit findings and CAPA implementation were discussed in review meetings as for example in Management Review Meeting carried out on 18.07.2019

**Proficiency testing**
An SOP for ensuring the validity of test results was presented. The laboratory participated in PT provided by LGC (report issued on 26.07.2019) for assay determination by UV and by HPLC (report issued on 12.04.2019). The laboratory had established a system for evaluating Proficiency Test results and for investigating and applying CAPAs in case Z value limits were exceeded. Proficiency Test were selected based on the laboratory scope as approved by Pakistan National Accreditation Council (PNAC).

Out of Specifications (OOS)
The procedure on handling OOS results was reviewed

## 3. Control of documentation

A procedure on management and control of documentation was presented. Four levels of documentation were defined

- Level 1: QM and Quality Policy,
- Level 2: Procedures,
- Level 3: Work instructions,
- Level 4: Quality forms

The procedure described issue, distribution, review, retrieval and withdrawal of the different documents. It also included appropriate instructions on codifying the documents. Spot checks on codification and distribution of procedures and working instructions were made. In addition, a procedure for writing various QMS documents was available. This SOP elaborated the complete format and guidelines for drafting QMS documents

## 4. Records

Original observations, calculations and derived data, calibration, validation and verification records and final results, were retained. The records included the data obtained and recorded on analytical worksheets**.**


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## 5. Data processing equipment

There was software available for registering incoming samples and monitoring sample analyses. "Drug Testing & Monitoring System (DTMS)" was developed by Punjab Information Technology Board (PITB) who was also the owner of the software and provided service and technical support. Data was backed up on the hard drive of the computer used to register the sample, on the laboratory server and the PITB server.

Empower 3 software was used for Waters HPLCs. It was noted that there was no procedure in place describing the access levels and privileges.

## 6. Personnel

There were approximately 40 people working in the laboratory. It was noted that a number of posts were vacant. Generally, the laboratory had personnel with the necessary education, training, technical knowledge and experience for their assigned functions. The job descriptions of the QMS manager, Hi Tech laboratory in charge and analysts were reviewed and found adequate.

### Training

A procedure for training was in place. Trainings were categorized in:

- Quality (awareness of ISO 17025 and Quality Manual),
- Safety (Safety Manual and safety procedures),
- General Procedures and requirements,
- Techniques

The effectiveness of trainings was assessed with written or oral tests. All new staff had to undergo induction training. Competency assessment were conducted to identify training needs. A training schedule (December 2018 – December 2019) was in place. Competency trainings were conducted whenever analysts were rotated from one section of the lab to another. UV-VIS spectroscopy, HPLC polarimetry and flame photometer competency trainings were reviewed. Trainings on the importance of PPE, biosafety and biosecurity among others were also reviewed. Training records (including assessment records and signed attendance sheets) were available.

## 7. Premises

The laboratory was housed in a three-story building. Sample reception, registration and storage facilities were established on the ground floor. The analytical laboratories and water treatment plant were found on first floor. On the second floor the microbiological laboratory (out of inspection scope) and reference and working standard room were established. Retained samples were stored in an air-conditioned room on the third floor. Premises were designed to suit the functions and operations to be conducted in them. Rest and refreshment rooms were separate from laboratory areas. The laboratory facilities had adequate safety equipment located appropriately and measures were in place to ensure good housekeeping.


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## 8. Equipment, instrument and other devices

The laboratory was adequately equipped with test equipment, instruments and other devices for the performance of the tests and/or calibrations, validations and verifications. It was also equipped with adequate work benches, work stations and fume hoods.
Calibration status labels were attached to instruments. Laboratory instruments had instrument log books and procedures for calibration and use. HPLC columns were stored in a separate room and there was logbook available. Spot checks on the following equipment were made during the inspection:

- 2 Shimadzu HPLC operating on Lab solution software
- 5 Waters HPLC operating on Empower 3.0 software
- UV spectrophotometer 1800
- Karl Fischer Titrator
- Metler Toledo balance B731468622
- Tablet Multi Tester (Pharma Test PTB311E)

## 9. Contracts

Analytical testing was not subcontracted. In case any analytical test could not be performed in-house, a letter was sent to the inspector or legal entity informing them that the analysis could not be carried out. Provincial Quality Control Laboratory was tasked to send the sample to another laboratory if the test could not be carried out.
There was a procedure based on tender approved by Designing Committee DTL and three quotations had to be evaluated. All supplies had to be inspected before acceptance for use. The Procurement/Store Officer was responsible for preparing a list of suppliers and service providers. Supplier evaluation was performed on an annual basis. Records of such assessments were maintained. Suppliers not meeting the established standards were disqualified for procurement in that year. An approved vendor list for chemicals was available. Spot checks on the annual qualification of suppliers were performed

## 10. Reagents

In general, there were procedures in place for the preparation and storage of reagents. Appropriate labels were used. Titration solutions were appropriately labeled. There were dedicated areas for storage of reagents.

Water
There were two water purification systems in the laboratory. The first purification system used a cascade of filters including a RO filter and provided HPLC grade water. The second system generated water with conductivity less than 10 µS/cm. Instructions on the generation and testing of HPLC water were detailed in SOPs

## 11. Reference substances and reference materials

Reference and working standards were purchased from suppliers qualified by the Provincial Quality Control Laboratory. In the past procurement was assigned to provincial laboratory currently the laboratory can purchase directly from the centrally approved suppliers. Reference and working standards were stored under appropriate conditions in refrigerators and they were assigned internal id numbers. A procedure for handling reference and working standards and monitor inventory and use was available. A spreadsheet for monitoring quantities and expiry dates was maintained. Working standards traceable to compendial standards were mostly used.


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

Procedures on management of equipment, qualification of equipment and calibration of instruments were available as well as a master list for laboratory equipment. No VMP was presented. An annual programme for qualification/calibration of equipment was available but it did not cross-refer to the master list of equipment. Software and computerized systems were not included in the annual qualification programme. There were instructions available for daily verification of equipment. Appropriate CAPA were implemented following the inspection

## 13. Traceability

Test results were generally traceable to analysts, analytical instruments, equipment, reagents, reference substances and test procedures. Samples were labelled with barcodes and registered in a database. A procedure on control of records was presented

## 14. Incoming samples

Incoming samples were received in the office and registered in a computerized system and allocated to analysts. Registered samples were usually transferred to the analytical laboratory within a short period of time. There was software available for registering incoming samples and monitoring sample analyses. "Drug Testing & Monitoring System (DTMS)" was developed by Punjab Information Technology Board (PITB) who was also the owner of the software and provided service and technical support. The system allowed for the registration of samples, printouts for archiving registration, issue of barcodes for samples and analyses. A user manual was available. It was issued by PITB and incorporated in the QMS as working instructions (external documentation). Drug Testing Laboratory automation programme is an initiative taken by the Punjab Government to improve the authenticity of test performed on different types of drugs. A web application DTMS was developed to provide secure access to real time statistics of the laboratory regarding drug testing. Key features included: Secure access to web application (DTMS), Customized Dashboards and statistical analysis, 24/7 based availability of reports and test results, digitalization of all process related to drug testing, maintenance of transparency through barcode, picture capturing and biometrics

## 15. Analytical worksheet

Analytical worksheets specified the following:

- Method file name
- Sequence file name
- Tests to be done (assay/dissolution)

## 16. Validation of analytical procedures

The laboratory used USP, International Pharmacopoeia and manufacturers validated methods as reference test procedures. If no compendial method was available, a manufacturer's method would be used. It was noted that a procedure on Analytical method transfer was put in place for the first time on 04.07.2019. Before this date no analytical method transfer was performed. The procedure on method transfer was deficient since it did not describe in detail the selection of critical method parameters that had to be verified. Appropriate CAPA were implemented following the inspection


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## 17. Testing

There were procedures in place for allocating samples, recording samples on worksheets and analyses on equipment logbooks. There were instructions in place for use of equipment and for carrying out the analyses. Test results were recorded and signed by analysts and reviewed by senior analysts.

## 18. Evaluation of test results

Test reports were reviewed against acceptance criteria that address accuracy, clarity and objectivity. Results were recorded on analytical worksheets and in the LIMS. Results are analysed statistically to evaluate the quality, efficacy and safety of the product. After compilation of raw data, a senior analyst cross checks the results of testing and then these results are approved by Technical Manager. The results along with the raw data are kept for ten years and could easily be retrieved as per requirement. If any doubt arises retest and verification of raw data is followed.

## 19. Certificate of analysis

There were two procedures in place for releasing analytical reports. In case of test results meeting specifications, a total of four original copies were generated; two copies for the authority sending sample and one copy for PQCB and DTLF respectively. In case of verified OOS results an additional copy of the OOS report is attached. The results of the tests were also posted on a restricted web link to be accessed by the relevant inspector or authority. There was a review process taking place before a certificate was issued and signed.

## 20. Retained samples

Retained samples were packed in carton boxes and the list of their barcodes was placed on the outer side box with barcode of that month. Retained samples meeting specifications were kept for a period of three months and in case of falsified samples they were stored for up to 10years.

## 21. Safety

The laboratory had relevant procedures and safety manual in place. Safety control measures against chemicals detailed first aid for be provided for each of the chemicals used by the laboratory.
Procedure for handling spilled materials which lay guidelines for handling spilled chemicals and the procedure for the fire extinguisher were reviewed. The safety manual was made available. Training records on the safety/safety manual were also available


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| Part 3 | Conclusion – Inspection outcome |
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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, ***Drugs Testing Laboratory Faisalabad***, located at ***A block, near DPS School G.M. Abad, Faisalabad, 38000, Pakistan*** 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 |
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1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 1.
   ***Short name: WHO GPPQCL Guidelines*** or ***TRS No. 957, Annex 1***
   http://www.who.int/medicines/publications/44threport/en/

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

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   ***Short name: WHO TRS No. 970, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/
4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   ***Short name: WHO TRS No. 929, Annex 4***
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
   ***Short name: WHO GDRMP guidance*** or ***WHO TRS No. 996, Annex 5***
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

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. 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

8. 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

9. 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

10. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-forth 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

11. 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, 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


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