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

Part 1	**General information**
Laboratory details	
Name	National Institute of Drug Quality Control of Vietnam (NIDQC)
Address	48 Hai Ba Trung Street, Hoan Kiem District, Hanoi city, Vietnam
GPS coordinates	21°01'31.9"N 105°50'59.8"E
Inspection details	
Date of inspection	21, 24 and 25 February 2020
Type of inspection	Routine
Introduction	

Brief description of testing activities

Type of analysis	Finished products	Active pharmaceutical ingredients
Physical/Chemical analysis	pH, density, refractometry, viscosity, loss on drying, water content, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, particulate matter test	pH, density, refractometry, specific optical rotation, viscosity, loss on drying, melting point, water content, heavy metals, sulphated ash, acid insoluble ash, acid value, iodine value, ester value, acetyl value, peroxide value, saponification value
Identification	HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-Vis spectrophotometry, IR, AAS, ICP/MS	HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, UV-Vis spectrophotometry, IR, FTIR, AAS, ICP/MS, chemical reaction
Assay, impurities and related substances	HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, IR, UV-Vis spectrophotometry, AAS, ICP/MS, fluorimetry, volumetric titrations, amperometry, potentiometry, nitrogen assay	HPLC (UV-Vis, DAD, fluorescence, light scattering detection), LC/MS/MS, GC (FID, ECD), GC/MS, TLC, HPTLC, IR, UV-Vis spectrophotometry, AAS, ICP/MS, fluorimetry, volumetric titrations, amperometry, potentiometry, nitrogen assay, thermal analysis (DSC/TGA)

	Micro-biological tests	Sterility test, microbial purity, test for pyrogens, bacterial endotoxins test (LAL), microbial assay	Sterility test, microbial purity, test for pyrogens, bacterial endotoxins test (LAL), microbial assay
	Stability studies	WHO conditions	WHO conditions

General information

29/07/1957 The Minister of Health signed the Decree No. 845-BYT/ND to establish the Drug Quality Control Laboratory under the direct supervision of the Ministry of Health. It was the predecessor of the National Institute of Drug Quality Control as present.

13/04/1961 The Minister of Health had Decision No. 324/BYT-QD, to re-establish the Drug Quality Control Laboratory to become the Institute of Medicinal Materials consisting of two clusters: Herbal Medicinal Materials and Drug Quality Control.

04/01/1971 The Council of the Government had Decree No. 03/CP regarding the adjustment and re-organization of the Ministry of Health, thereby the drug quality control cluster was split and re-organized to become the Institute of Drug Quality Control under direct supervision of the Ministry of Health.

18/04/2006 The Prime Minister signed Decision No 621/QD-TTg on re-arrangement and re-organization the service units under direct supervision of the Minister of Health outside the scope of the Decree 49/2003 / NĐ-CP, thereby to rename the Institute of Drug Quality Control as the National Institute of Drug Quality Control.

The National Institute of Drug Quality Control has experienced sixty three (63) years (1957-2020) of formation and development. The drug quality control network, with the National Institute of Drug Quality Control as the leader, has grown up and developed along with the development of the pharmaceutical sector of Vietnam. In each period and each era, the Institute together with the drug quality control network had fulfilled the responsibilities in controlling and monitoring the quality of drugs for the protection, care and improvement of people's health.

The National Institute of Drug Quality Control is a service unit under the direct supervision of Ministry of Health; being the highest drug quality control unit at the central level in Vietnam; having legal status, its own stamp and account as allowed by the laws.

The Institute has the function of scientific research; network supervision; training of specialized personnel; quality analysis and monitoring of drugs (except for vaccines and diagnostic bio-products), cosmetics and others (generally called as drugs); arbitrator in disputes, complaints about the quality of drugs; advise to the Ministry of Health on drug quality control network planning and development as well as technical measures to control and monitor the drug quality as appropriate to the socio-economic development conditions of the country in each period.

History

NIDQC was last inspected by the WHO in October 2016.

Laboratory was inspected by the following authorities:

Authority	Date/s of inspection	Scope of inspection
Bureau of Accreditation (BoA) - Ministry of Science and Technology	January 2015	Evaluation of supervision
Bureau of Accreditation (BoA) - Ministry of Science and Technology	November 2015	Routine inspection
Drug Administration of Vietnam - Ministry of Health	March 2016	Routine inspection
Bureau of Accreditation (BoA) - Ministry of Science and Technology	April 2017	Evaluation of supervision
Bureau of Accreditation (BoA) - Ministry of Science and Technology	November 2018	Routine inspection
Bureau of Accreditation (BoA) - Ministry of Science and Technology	December 2019	Evaluation of supervision

Brief report of inspection activities undertaken - Scope and limitations	
Areas inspected	See section 2 below
Restrictions	N/A
Out of Scope	Center for Bioequivalence studies
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
ALCOA - plus	Attributable, legible, contemporaneous, original and accurate which puts additional emphasis on the attributes of being complete, consistent, enduring and available
API	Active pharmaceutical ingredient
BE	Bioequivalence
BET	Bacterial endotoxin test
BP	British Pharmacopoeia
BSC	Biological safety cabinet
CoA	Certificate of analysis
EDI	Electro deionization
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GC	Gas chromatography or Gas chromatography equipment
GLP	Good laboratory practice
GMP	Good manufacturing practices
HEPA	High Efficiency Particulate Air
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KF	Karl Fisher titration
LC/MS	Liquid chromatography - Mass spectrometry
LIMS	Laboratory information management system
MB	Microbiology
MR	Management review

NC	Non-conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
PCR	Polymerase chain reaction
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
QM	Quality manual
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RH	Relative humidity
RO	Reverse osmosis
RS	Reference standard
RSD	Relative standard deviation
SOP	Standard operating procedure
T	Temperature
TAMC	Total aerobic microbial count
TLC	Thin layer chromatography
TYMC	Total yeast mold count
URS	User requirement specification
USP	United States Pharmacopoeia
UV	Ultraviolet
UV-VIS	Ultraviolet-visible spectrophotometry or spectrophotometer
WS	Working standard

Part 2	Summary of findings and recommendations

1. Organization and management

The laboratory was legally authorized and 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. Draft commitment form (for leaders, unit leader and staff) was presented to inspectors.

2. Quality management system (QMS)

The laboratory had established, implemented and maintained a QMS appropriate to the scope of its activities and the elements of quality system were documented. The QMS was ISO/IEC 17025: 2017 certified. Various SOPs were reviewed which were easily retrievable and version control appeared to be appropriate.

Quality Manual (QM)

The Quality Manual was discussed. The QM was prepared by the Quality and Technical Management Unit. The QM described the quality policy, quality objectives, organizational structure, responsibilities and working relationships between the units and related procedures in accordance with the requirements of ISO/IEC 17025: 2017; good laboratory practice (GLP) and prequalification.

QM system was structured into three (3) levels:

- Level 1: Quality Manual (QM)
- Level 2: Procedures (SOPs), Protocols, Specifications and Analytical Methods.
- Level 3: Forms

Management reviews (MR)

SOP "Management Review" indicated that reviews were performed monthly and annually. The results of the management review were documented by the Department of Planning and General Affairs. The results of the management review formed the basis for the determination of the goals, action plans, and quality targets for the following year.

The annual management review for 2019 was discussed. The review period was determined as per the financial year (December to November).

Organization structure

A chapter in the QM covered the legal status, organizational structure, functions, duties and authorities of NIDQC. The following content was covered:

- Organizational structure
  - Leadership
  - Functional departments
  - Technical laboratories/centers
- Functions, responsibilities and authority

Key personnel included the Board of Directors and the Heads of laboratories/departments/units/centers.

Change controls (CC)
SOP "Change Control" specified how to implement changes to the technical or management systems to ensure that all changes were identified, reviewed and approved.
Changes were classified as:

- Major
- Minor
- Urgent

Deviations
SOP "Control of Nonconforming Work" indicated that non-conformances should be classified as:

- Major
- Minor

When major non-conformances were detected, the Director Board or the Commissioned Head of the department/unit/center should halt the activity, change the analyst, investigate the causes, evaluate the non-conforming work, conduct corrective actions and improve procedures. The testing/calibration certificates related to the non-conforming work should be retained and reported to the Director Board. If non-conformances related to testing/calibration test results had been issued, the Head of Planning and General Affairs department or Calibration unit notified the customers as soon as possible and corrective actions should be done immediately.

When minor non-conformances were detected, the non-conformances would be reported to the Head of department/unit/center who would be responsible for evaluating the non-conforming work, conducting corrective actions and deciding on the acceptability of the non-conforming work.

Complaints
SOP "Review and Resolve of Complaint" and complaint register for 2019 were discussed. Complaints were received by Planning and General Affairs department and sent for investigation to the respective department.

Corrective and preventive actions (CAPAs)
SOP "Risk Management, Corrective and Preventive Actions, Improvement" defined the activities to manage risk, take corrective and preventive action or improvement when dealing with non-conforming work or compliance with policy and QMS procedures.

Internal audits
SOP "Internal Audits" indicated that internal audits were required to be performed annually. According to the SOP, internal audits could be carried out more frequently in the event of:

- Customer complaints
- Non-conforming work
- Upon agreed request from customers
- Supplementary assessment following implementation of corrective actions

The Technical and Quality Management unit was responsible for establishing the audit team which was approved by the Director. The findings were addressed by completing the Corrective Action Form (VKN/BM/08.01).

Proficiency testing
Laboratory participates in External and internal proficiency testing schemes.

Out of Specifications (OOS)
SOP "Treatment of OOS Results", flow charts (separate for physical/chemical/BET and microbiological) and OOS investigation forms and a number of OOS investigations were discussed.

Selection of service providers and suppliers
SOP "Purchasing Services and Supplies" was discussed. This procedure was applicable to purchase services and supplies. Approved reagents supplier list and service providers list were available and updated annually.

3. Control of documentation
SOP "Control of Documents" was discussed. Documented procedures were in place. Generally, documents had a unique identification number, version number and date of implementation. According to the procedure, documents were coded and prepared by Technical-Quality Management unit, Calibration unit or other units as assigned. Technical-Quality Management unit was responsible for retaining, managing and distributing documents. Documents were approved by the Director Board. Only one (1) original printout was available and was identified by the Director's signature and stamp. Copied documents had a "Controlled" stamp.

Documents should be reviewed and updated at least every three (3) years. Analytical raw data was stored for twenty (20) years.

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 in analytical worksheets.

5. Data processing equipment
SOP "Data Control and Information Management" was discussed. The procedure was applicable to all computers connected to analytical instruments and devices storing data, system documents and electronic data. The procedure defined 3 access levels. Procedure also explained data back-up.

The HPLC systems, GC system and UV spectroscopy equipment were linked to the computers operated by respective software's.

6. Personnel
Generally, the laboratory had sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions. Staff members undergoing training were supervised and were assessed on completion of the training. Personnel performing specific tasks were qualified in terms of their education, training and experience, as required. Current job descriptions were maintained. Laboratory had experienced and knowledgeable personnel.

Training
SOP "Training" and training schedule were discussed. Reviewed the training record for the microbiologist who was recruited in XX and found to be acceptable.

7. Premises

Facility No. 1 consisted of four (4) buildings:

- Building A
- Building B
- Building C
- Building D

Physical-chemical laboratory premises were spacious and were designed to suit the functions and operations to be conducted in them. Rest and refreshment rooms were separate from laboratory areas. Laboratory had storage facilities for storage of samples, and for reagents. Access to work or storage areas was fingerprint controlled. The laboratory facilities had adequate safety equipment located appropriately and measures were in place to ensure good housekeeping. Laboratory was equipped with adequate instruments and equipment, including work benches, workstations and fume hoods.

Microbiological laboratory

Access to the Microbiology laboratory was restricted to authorized personnel (password protected).

There were following laboratories accessed via airlocks:

- Storage and incubation area
- Preparation laboratory
- PCR laboratory
- Antibiotic/Positive control laboratory
- Microbial limit test laboratory
- Sterility test laboratory

The Apparatus cleaning room/handling of waste was accessed from within the Microbiology laboratory via pass-throughs and had a separate entrance from the Administration area. The Bacterial Endotoxin Test (BET) was performed in Facility 2 which was not inspected.

The clean rooms were requalified as per SOP “Clean Room Requalification Protocol”.

SOP “SOP for Quality Control of Media” described the requirements for the preparation, preservation and quality testing of the media.

The dehydrated culture media was stored under suitable conditions as indicated on the supplier’s label. Every batch of prepared and sterilized media used for sterility testing was tested as follows:

- pH of the media
- Sterility of media
- Growth promotion

The autoclaved media was stored at 2 - 8 °C. Media used “First-In - First Out”.

Requalification requirements were discussed:

- SOP “SOP FOR Requalification of Sterilization Oven”
- SOP “SOP FOR Requalification of Hyrayama HV 110 Autoclave”

Sterility testing
SOP "SOP for Sterility Test" was discussed. The review of the SOP was overdue.

Bacterial Endotoxin Testing (BET)
SOP "Bacterial Endotoxin Test using the Gel Clot Method" required the test to be performed according to the required pharmacopoeias. The gel-clot limit test was used to perform the BET test. Micropipettes were calibrated annually according to ISO 8655 "Piston-operated volumetric apparatus".

Documentation archive
Laboratory documents including analytical work sheets and raw data were stored in several locations.

8. Equipment, instrument and other devices

Generally, the laboratory had test equipment, instruments and other devices for the performance of the tests and/or calibrations, validations and verifications. Calibration status labels were attached to instruments. Laboratory instruments had "Instrument Logbooks".

As an example, dosage forms testing laboratory equipment/instrument calibration was discussed. List of equipment/instruments and calibration/maintenance schedule was presented for 2019 and 2020.

9. Contracts

Contract laboratories were not used.

10. Reagents

Reagents chemicals and flammable liquids were received and checked upon arrival. Receipt forms were completed manually. After receipt, reagents and chemicals were moved to the storage room, flammable/explosive reagents were stored in a separate storage room. The labels indicated expiry date/date of receipt and date of opening.

SOP "Management of Reagents and Chemicals" was discussed.

Water
Purified water (PW) used for analysis was produced in the laboratory by RO and EDI using the Millipore Elix system. Water storage tank was 200 L. To reduce biocontamination, the PW system was equipped with continuous circulation loop.

PW system was monitored on-line: TOC, conductivity, pH and T.

HPLC grade water was produced by Milli-Q water system. HPLC grade water system was monitored on- line (TOC and conductivity).

Gases
Gases N_2 and H_2 used in chromatography were procured.

11. Reference substances and reference materials

Secondary reference substances were prepared and standardized by the Establishment of Standards and Reference Substances laboratory. Secondary reference substances were supplied internally and externally. Standards were stored in walk in chamber under 2ºC - 8ºC. Chamber was equipped with alarm system. T was checked and recorded twice a day.

SOP "Establishment and Calibration of Reference Standards and Volumetric Solutions" was discussed. The laboratory prepared:

- Secondary reference substances
- Volumetric solutions
- Herbal reference substances.

For each reference substance laboratory had to prepare protocol specifying tests to be performed and specifications and acceptance criteria.

According to the SOP, API qualified for secondary reference standard was analyzed against Pharmacopoeia RS. Then dispensed. After dispensing, collaborative testing between two institute laboratories was carried out. As an example, preparation of Amoxicillin Trihydrate secondary reference substance for identification test and assay was discussed. Preparation and standardization of secondary reference standards was well documented.

Secondary reference substances were dispensed in amber color single use vials in a glove box. Register indicated re-test dates of secondary reference substances prepared in the laboratory was presented to the inspectors. Register was reviewed and updated monthly.

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

As an example of equipment/instrument calibration/verification HPLC Shimadzu was discussed.

13. Traceability

Test results were generally traceable to analysts, analytical instruments, equipment, reagents, reference substances and test procedures.

14. Incoming samples

Registration and labelling

Upon receipt, the sample received was checked for:

- Sample seal
- Packaging integrity
- Labelling

The quantity of samples should be adequate for at least three (3) repetitions of the analysis and for retention.

Receiver was responsible for sample coding and entering samples in the receiving logbook. Samples after being coded were divided into two equal portions, one portion was retained at the institute's sample retention section, the other was transferred to the respective laboratories.

15. Analytical worksheet

Analytical worksheets and calculations were checked by Head of respective laboratory. Each page of analytical worksheets was signed by Head of respective laboratory. Analytical work sheets were requested by analysts according to "Analytical Worksheets Monitoring Form". Analytical worksheets were printed, and issuance controlled by Head of the laboratory.

16. Validation and verification of analytical procedures

SOP "Development, Validation and Approval of Testing/Calibration Methods" was discussed.

APIs

Analytical procedures for active substances which have been described in pharmacopoeia monographs were considered validated. For example, testing conditions were the same as those described in the monograph and where the verification of suitability met the requirements of the monograph. According to the NIDQC policy, tests for related substances in pharmacopoeia monographs were considered validated when applicable to the control of the specified impurities. For unspecified impurities, the specific characteristics to be considered for validation were defined.

Medicinal products

When pharmacopoeia monographs were applied, measures should be taken that the excipients did not interfere in the analysis of the active substance. The following was applied:

- Analytical procedure fully validated by manufacturer: No validation required.
- Analytical procedure with no/insufficient validation data: Method suitability verification should be carried out

SOP also explained actions to be done in case:

- Analytical procedure had been fully validated by manufacturer
- Analytical procedure with no/insufficient validation data
- Method of a first manufacturer to be used for a product of a second manufacturer
- Method for an active substance to be used for a medicinal product
- Non-compendial method
- Compendial method

As an example, Zidalex suspension manufacturer in-house STP validation (identification and assay tests by HPLC) was discussed. Method was validated upon manufacturer's request.

17. Testing

SOP "Reporting Testing/Calibration Results" was discussed. According to the procedure automatic and manual integration was allowed. Requirements for manual integration was set up by method developer.

As an example, Ampicillin Capsules BP 500 mg, (market surveillance sample) analytical raw data was cross checked with equipment and standards usage logbooks. Traceability was ensured.

18. Evaluation of test results

SOP "Control of Testing/Calibration Quality" was discussed. Interim CoA was prepared by analysts and approved by the Head of laboratory.

19. Certificate of analysis (CoA)
Control and issuance of CoA was done according to SOP "Pathway of Samples". CoA was checked by Head of Planning and General Affairs department and signed by Director or Vice Director of the NIDQC.

20. Retained samples
Retained samples were stored according to the specified storage conditions for two (2) years from the date of receipt, TCH samples (validation) were stored one (1) year from the date of receipt. T and RH was controlled on-line and recorded every twenty (20) minutes. Daily printouts were available, however printout was not signed and approved.

21. Safety
Safety data sheets were available. Laboratory staff wore laboratory coats and eye protection googles. Adequate safety equipment was provided.

Part 3	**Conclusion – Inspection outcome**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***National Institute of Drug Quality Control of Vietnam (NIDQC***) located at ***48 Hai Ba Trung Street, Hoan Kiem District, Hanoi city*, Vietnam** 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 4	**List of WHO Guidelines referenced in the inspection report**

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

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

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. 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-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://www.who.int/publications-detail/978-92-4-000182-4

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