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

| **Part 1** | **General information** |
|---|---|
| **Laboratory Details** | |
| Name | Institute of Drug Quality Control (IDQC-HCMC) |
| Address | 200 Co Bac Street, District 1, Ho Chi Minh City, Vietnam |
| GPS Coordinates | 10°45'53.0"N<br>106°41'36.2"E |
| **Inspection details** | |
| Date of inspection | 17 - 19 February 2020 |
| Type of inspection | Routine |
| **Introduction** | |
| Brief description of testing activities | |

| **Type of analysis** | **Finished products** | **Active pharmaceutical ingredients** |
|---|---|---|
| Physical/ Chemical analysis | pH, loss on drying, water content, optical rotation, disintegration, dissolution, density, uniformity of dosage unit (mass, content), container content, foreign and particular matter, deliverable volume | pH, loss on drying, water content, melting point, sulphated ash, acid insoluble ash, residual solvents, limit test, heavy metals, residue on ignition, TOC, water conductivity |
| Identification | HPLC (UV-VIS, Fluorescence, RI, DAD, MS detection), GC (FID, MS detection), AAS, FTIR, UV-VIS spectrophotometry, TLC, chemical reaction | HPLC (UV-VIS detection, RI, DAD, MS detection), GC (FID, MS detection), AAS, FTIR, UV-VIS spectrophotometry, TLC, chemical reaction |
| Assay, impurities and related substances | HPLC (UV-VIS, Fluorescence, RI, DAD, MS detection), GC (FID, MS detection), AAS, UV-VIS spectrophotometry, volumetric and potentiometric titrations, IR | HPLC (UV-VIS, Fluorescence, RI, DAD, MS detection), GC, UV-VIS spectrophotometry, volumetric and potentiometric titrations, IR |
| Micro-biological tests | Sterility test, microbiological examination of nonsterile product, bacterial endotoxins test, pyrogen, microbial assay of antibiotics | Sterility, microbiological examination of nonsterile product bacterial endotoxins test, pyrogen, microbial assay of antibiotics |

<table>
<tr><td>General information</td><td>The Institute of Drug Quality Control, Ho Chi Minh City (IDQC-HCMC) was established in January 1977 by Decision No. 85/TC-QĐ BYT of Ministry of Health (MoH), Vietnam. IDQC-HCMC is a National Quality Control Laboratory which functions to provide analytical services for the quality and safety of drugs and cosmetics in the southern region of Vietnam, from Da Nang to Ca Mau province.<br><br>IDQC-HCMC is a semi-autonomous government agency under the Vietnamese MoH. IDQC-HCMC is providing quality testing services of medicines and cosmetics to the government of Vietnam and private manufactures and suppliers. IDQC-HCMC has established, implemented and maintains a quality management system.<br><br>IDQC-HCMC employees 150 analytical and support staff dedicated to providing quality testing and calibrations services to its customers. IDQC-HCMC analyzes approximately 3000 pharmaceutical, cosmetics, and herbal medicines samples annually for the southern region of Vietnam.<br><br>IDQC-HCMC provides the following testing activities to its customers:<br>• Physical and chemical analysis, identification, assays and impurities testing of Active Pharmaceutical Ingredients (API), capsules, tablets, injectable, powders and suspensions.<br>• Biological assay of antibiotics, test for sterility, tests for microbial contamination using microbial and molecular biology methods, endotoxin testing, pyrogen.<br>IDQC-HCMC’s objectives for the testing and calibrations services are established by the Director and Vice Directors and from the MoH’s mandate.</td></tr>
<tr><td>History</td><td>IDQC-HCMC was last inspected by the WHO in October 2016.<br>Laboratory was inspected by the following authorities:<br><br>
<table>
<tr><th>Authority</th><th>Date/s of inspection</th><th>Scope of inspection</th></tr>
<tr><td>Drug Administration Department of Vietnam (DAV), Ministry of Health</td><td>November 2015</td><td>• Quality System Management<br>• Chemical, Physical and Microbial Testing<br>• Instrument Calibration</td></tr>
<tr><td>Bureau of Accreditation (BoA), Vietnam</td><td>January 2016</td><td>• Quality System Management<br>• Chemical, Physical and Microbial Testing<br>• Instrument Calibration</td></tr>
<tr><td>Bureau of Accreditation (BoA), Vietnam</td><td>December 2016</td><td>• Quality System Management<br>• Chemical, Physical and Microbial Testing<br>• Instrument Calibration</td></tr>
<tr><td>Bureau of Accreditation (BoA), Vietnam</td><td>April 2018</td><td>• Quality System Management</td></tr>
</table></td></tr>
</table>

| | | | |
|---|---|---|---|
| | | | • Chemical, Physical and Microbial Testing<br>• Instrument Calibration |
| | Bureau of Accreditation (BoA), Vietnam | December 2018 | • Quality System Management<br>• Chemical, Physical and Microbial Testing<br>• Instrument Calibration |
| | Bureau of Accreditation (BoA), Vietnam | December 2019 | • Quality System Management<br>• Chemical, Physical and Microbial Testing<br>• Instrument Calibration |
| | Drug Administration Department of Vietnam (DAV), Ministry of Health | August 2020 | • Quality System Management<br>• Chemical, Physical and Microbial Testing<br>• Instrument Calibration |

| **Brief report of inspection activities undertaken – Scope and limitations** | |
|---|---|
| Areas inspected | See section 2 below |
| Restrictions | N/A |
| Out of Scope | N/A |
| **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 |
| ATCC | American Type Culture Collection |
| 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 |
| QAU | Quality assurance unit |
| 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 |
| STP | Standard test 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 |
|---|---|

***Brief summary of the findings and comments***

**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. Staff confidentiality declarations were available.

**2. Quality management system (QMS)**

The laboratory had established, implemented and maintained a quality management system appropriate to the scope of its activities, the elements of quality system were documented. Quality System of IDQC-HCMC was established, operated and maintained in accordance with ISO/IEC 17025 standard and WHO-GPPQCL guidelines. QMS was ISO/IEC 17025 certified.

Quality Manual (QM)

The IDQC-HCMC QM was originally written in 2001 and was revised and amended periodically. The Quality Assurance Unit (QAU) was to maintain the QM and it was approved by the Director. The content of QM was periodically revised and updated via internal audits and management reviews to ensure compliance with test/calibration activities. The QM covered quality policies, objectives and identified procedures for the QMS of IDQC-HCMC that should comply with WHO- GPPQCLP and ISO/IEC 17025. Distribution of QM was controlled as all IDQC-HCMC departments had a controlled copy.

Change controls (CC)

SOP "Change Control" applied to the operation in IDQC Quality System. There were several change control levels:

- Emergency
- High
- Medium
- Low

SOPs "Good Documentation Practices" and Control of Non-conforming Works" were discussed.

Complaints

SOP "Review and Solve the Customer Complaint" and registers for 2018 and for 2019 were discussed. Complaints were received by Planning department and forwarded to the Director. Director had overall responsibility for complains. Director assigned responsible person for dealing with complains from respective departments. Investigation was carried out by responsible unit manager. CAPA procedure was applied if required.

Corrective and preventive actions (CAPAs)

SOP "Corrective and Preventive Action" was discussed.

In the event internal non-conforming work was detected, the Head of the relevant unit(s) was responsible for resolving and reporting it to the top management.

In the event external non-conforming work was detected (nonconforming test/calibration results), the Institute was required to immediately notify the customer, investigate the nonconformance, apply appropriate corrective action, to include but not limited to providing new test/calibration results. The release of new test results and withdrawal of old ones was decided by top management.

The Head of QAU was responsible for monitoring results of CA to ensure that the CA taken were effective before closure.

Risk assessments

SOP "Risk Management" was briefly discussed. Risks were identified as:

- Critical
- Medium
- Minor
- Remote

Management reviews (MR)

SOP "Management Review" and last meeting minutes were discussed. MR meetings were performed annually. Standard agenda was specified. Additionally, review meetings of non-conforming work were performed weekly.

Internal audits

SOP "Internal Audit" described the areas to be audited and responsibilities associated with the internal audit process. The auditor needed to be independent of the activity. The Head of QAU was responsible for compiling the annual internal audit schedule, setting up the audit program, selecting and establishing auditor groups and organizing audits. Internal audits were carried out in accordance with ISO/IEC: 17025 standard and WHO GPPQCL guidelines. Check lists were used to conduct audits. An internal audit report was sent to the top management.

The internal audit schedule of IDQC-HCMC for 2019 was discussed and this ensured that all elements of the QMS were audited. The audit findings were classified as major, minor or as observations.

Proficiency testing

Annually, IDQC-HCMC participated in the proficiency testing program from:

- Bureau of Drug and Narcotic (BDN), Thailand
- Bureau of Cosmetics and Hazardous Substances, Thailand
- EDQM, France
- National Institute of Drug Quality Control (NIDQC), Vietnam
- IFM Quality Services PTY LTD, Australia
- NOMCoL Asia - Pacific/PQM-USP
- National Institute for Food Control, Vietnam

Every two years IDQC-HCMC organized the proficiency testing programme.

Out of Specifications (OOS)
SOP "Handling Out of Specification Results" and its flow chart were discussed. This SOP was related to the chemical tests, including physical tests. According to the SOP, OOS results should be trended annually.

In the case of the microbiological OOS, the following SOPs described the procedures for recording and investigation of out-of-specification results:
- SOP "Microbiological Laboratory Handle Procedure for Out of Specification"
- SOP "Handling for the Suspected or Out of Specification (OOS) Results in Bacterial Endotoxin Test"

Selection of service providers and suppliers
SOP "Selection and Receipt of Purchasing Services" was discussed. SOP was applicable to selection suppliers of solvents, reagents, equipment and instruments.

**3. Control of documentation**
SOP "Document Control" was discussed. Generally, documents had a unique identification number, version number, effective date and next review date, distribution of documents was controlled. A system of change control was in place to inform staff of new and revised procedures. Both electronic and paper records were kept for five (5) years.

Documents were organized in four (4) levels:
- QM
- Procedures
- Work instructions
- Records

A master list which identified the current version status, effective date and next review date was established and available to IDQC-HCMC staff.

SOP "Record Control" was discussed.

**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. The records included the data obtained and recorded in analytical worksheets. Upon completion of the data review process, it is the responsibility of the Planning Department to ensure that the electronic version of the report was tamper-proof by generating a "read-only" formatted copy for distribution. Analytical test records and calibration reports were stored for ≥ twenty (20) years, clinical research and BA/BE were stored for ≥ fifty (50) years.

**5. Data processing equipment**
SOP "Operation Manuals, Maintenance and Controls of Analytical Computer Network" was discussed. SOP specified five (5) user levels.

## 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.

SOP "Recruitment of Public Employees" was discussed.
Discussed the assignment of work/job descriptions for a number of personnel. The job description detailed the assigned work/Request for results of task performance/signature.

Job descriptions for the following personnel were briefly discussed:

- Standard and Reference Standards Establishment
- Microbiology Analysis

Laboratory employed 150 staff members.

Training

SOP "Training" was discussed. The SOP described the process for training of new recruits and current employees. Top management approved the training program. Head of QAU had responsibility to monitor and ensure compliance to the training program.

## 7. Premises

Physical-chemical laboratory 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. Laboratory was equipped with adequate instruments and equipment, including work benches, workstations and fume hoods.

Microbiology and Pharmacology (BET test) laboratories were designed to suit the operations to be carried out in them. Access was restricted to authorized personnel.

The Microbiology laboratory had the following rooms:

- Gowning room
- Media preparation room
- Microorganism inoculation room
- Microbiological assay of antibiotics room
- Microbiological limit testing room
- Sterility testing room (Sterility testing was carried out in a class A biological safety cabinet located within a class B clean room)
- Results interpretation room
- Washing and cleaning equipment room

## 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".

## 9. Contracts

SOP "Subcontracting of Testing/Calibration" was discussed. According to the SOP, top management was responsible to choose and approve sub-contractors. Approved sub-contractors list was reviewed annually.

## 10. Reagents

SOP "Selection and Receipt of Purchasing Services" was discussed. Selection of suppliers was done by the Logistics department. Individual forms were available for reagents. Suppliers were evaluated, and separate forms were available from Analytical, Accountant and Logistics departments. Approved supplier's list was available. Reagents were purchased in accordance to the Vietnamese state regulations. All purchase orders were reviewed and approved by top management. Reagents, chemicals and flammable liquids were received and checked and then distributed to the respective laboratories. According to the SOP, supplier's evaluation was performed annually.

SOP "Regulations for Labelling Reagents and Solutions" and SOP RG/P-QA-01 "Chemicals and Reagents Control" were discussed.

Reagents received in the laboratories bear the date of the receipt of the reagent, expiry date and date of opening.

Labels of the solution prepared in the laboratory should contain the following information:

- Name and chemical formula
- Concentration
- Standardization factor
- Expiry date
- Storage conditions
- Preparation date
- Name of person who prepared reagent

Water

Purified water (PW) was used for all types of drugs and API analysis. PW was generated by reversed osmosis and tested according to the USP. Chemical and microbiological tests were performed weekly.

## 11. Reference substances and reference materials

Secondary reference substances were prepared and standardized by Reference Substances Establishment department. Secondary reference substances were supplied to internally and externally.

SOP "Re-examination for Chemical Reference Standards" and "General Procedure for Production of ASEAN RS" were discussed. According to the SOP, bulk material/API should be evaluated and pass all tests specified in the pharmacopoeia and or manufacturers STP. Acceptance of the secondary reference standards were based on secondary standard test results. If tests results were within specifications (compared with original CoA) secondary standards were qualified. Tests were not carried out of primary standards to compare results.

As an example, preparation of Prednisolone base standard was discussed. Secondary reference substances were dispensed in amber color vials for single use in a glove box. Register indicating re-test dates of secondary reference substances prepared in the laboratory was presented to the inspectors.

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

Calibration of laboratory instruments and equipment was performed by calibration staff from each unit.
Calibration/verification schedules 2019 and 2020 for Formulation Analysis and API Analysis departments were presented to the inspectors.
Spot checks showed that schedules were followed. Maintenance schedule for 2020 was presented to the inspectors.

**13. Traceability**

During inspection the following sample was tracked:
Ciprofloxacin 500 film-coated tablets, (market surveillance sample), no discrepancies noted. Test results were traceable to analysts, analytical instruments, equipment, reagents, reference substances and test procedures.

**14. Incoming samples**

IDQC-HCMC analyzed the following samples:

- Upon manufacturers request (sample analysis and method validation)
- Market surveillance samples (collected by IDQC-HCMC sampling unit)
- Market surveillance samples (collected by police or inspectors

IDQC-HCMC market monitoring sampling plan was created annually by Planning department and approved by Director Drug Authority, Vietnam.

Incoming samples were stored in sample receipt room (Room temperature, 2 - 8 ℃ and 8 - 15 ℃).

Retention samples were stored in a separate room (Storage conditions - room temperature) for two (2) years after sampling or date of receipt.

Registration and labelling

SOP "Handling of Test Samples and Storage Samples", SOP "Review of Request, Tenders and Contracts for Testing Calibration" and SOP "Flow Chart of Testing Sample" were discussed. Upon receipt, seal and labels were checked and sample information recorded in the logbook containing the following information:

- Name of the customer
- Manufacturer
- Sample name
- Batch/lot
- Manufacturer date
- Expiry date
- Quantity (at least for three tests)
- Test request
- Specification
- Date of delivery
- Mane of sender
- Description of samples
- Storage conditions

SOP "Printing and Stamping Barcodes for Registration Number Sample" was discussed. Each sample had sample identification barcode which followed that sample from receipt till issuing CoA.

**15. Analytical worksheet**
SOP "Document Control" specified analytical worksheets template.

**16. Validation of analytical procedures**
Standard methods were used, whenever possible, or unless otherwise specified by the regulations or the customer. The pharmacopeia methods were called "standard methods" and should be verified and non-standard methods should be validated.

SOP "Methods, Method Validation and Verification" and SOP "Establishment and Evaluation of Testing Method Developed by IDQC" were discussed.

A number of analytical method validations were discussed.

**17. Testing**
SOP "Testing, Controlling and Evaluating the Results" was discussed. According to the SOP, sample information (For example: registration No., dosage form, batch No. etc.) should be checked. Calculated results were transferred to the sample management software. Calculations were done using excel sheets and manually by calculator. Excel sheets used for calculation were validated.

Microbiological tests
The following tests were performed:
- Sterility test
- Microbial limit tests
- Microbiological antibiotic assays

Preparation and control of media and types of media used:
SOP "Preparation, Preservation and Growth Promotion Test of Culture Media" was discussed. Media was steam sterilized using the manufacturer's recommendations. Growth promotion testing was performed on all media on all batches prepared using ATCC cultures.

SOP "Method Validation in Biological Testing" required the following pharmacopoeia methods to be validated:
- Sterility testing
- Microbial limit test
- Microbiological antibiotic assays

SOP "Setting up Negative and Positive Controls - Verification of Antimicrobial Activity" and SOP "Management of Reference Strains" were discussed. The SOP detailed the receipt, "propagation", preservation/storage, checking and use and treatment of micro-organisms after use.

The reference cultures were stored according to the supplier's recommendations for each strain. The working stocks were not sub-cultured more than five (5) generations/passages from the original reference strain. Purity and identification checks were performed.

SOP "Calibrating guide of autoclave" was discussed.

The Pharmacology department performed the Bacterial Endotoxin Test (BET). Two (2) techniques were used to perform the BET, the gel-clot technique and the turbidimetric technique.

SOP "Bacterial Endotoxin Test by Gel-Clot Technique" and SOP "Using the Cape Cod Pyros Kynetic Flex 32 Analyzer and Pyros EQS Software in Bacteria Endotoxin Test by Photometric Quantitative Technique" were discussed.

**18. Evaluation of test results**

SOP "Testing, Controlling and Evaluating the Results" and SOP "Assuring the Quality of Tests Results" were discussed. Planning Department was responsible for assigning the sample to the analyst according to competency. Test results were reviewed and signed by Unit management.

**19. Certificate of Analysis (CoA)**

SOP "Testing/Calibration Result Security and Control" was discussed. CoA`s were signed by Vice Director of the IDQC-HCMC.

CoA contained the following information:

- CoA number linked to the sample ID No.
- Name of sample
- Manufacturer
- Batch/lot number
- Expiry date
- Manufacturing date
- Registration No. (barcode)
- Drug Registration number
- Name of the person who submitted the sample
- Name of the unit who submit the sample
- Date of receipt of sample
- Test specifications
- Test method
- Description of sample

For market surveillance CoA was prepared at least in triplicate:

- One (1) was retained in IDQC-HCMC
- One (1) was sent to that company from where sample was collected
- One (1) was sent to the manufacturer/ importer
- One (1) for Drug administration of VN (MoH) if sample was not conformed

| 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, ***Institute of Drug Quality Control (IDQC-HCMC),*** located at ***200 Co Bac Street, District 1, Ho Chi Minh 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