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

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<tr><td>Address of inspected laboratory site</td><td>Bureau of Drug and Narcotic (BDN), Department of Medical Sciences, Ministry of Public Health, 88/7 Tiwanond Road, Muang Nonthaburi, 11000
Thailand</td></tr>
<tr><td colspan="2">Inspection details</td></tr>
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<tr><td>General information about the laboratory</td><td>The Bureau of Drug and Narcotic (BDN), Department of Medical Sciences was founded in 2002 by merging two existing divisions, the Division of Drug Analysis and the Division of Narcotics, to form a superior entity with higher management potential, per the State Administration Act Vol.5 B.E.2545 (2002)</td></tr>
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	and the Act on Organization of Ministries, Sub-Ministries, and Departments B.E. 2545. Currently, the BDN consists of seven major units: - Quality and Technical Development Section, - Chemical and Physical Testing Section, - Biological Testing Section, - Narcotics Section, - Reference Standard Center, - Thai Pharmacopoeia Section, and - Administrative Office. The Bureau of Drug and Narcotics, Department of Medical Sciences, is responsible for developing and setting up the standard methods and services for laboratory testing in pharmaceuticals and narcotics. The main activity of the Bureau is quality control of active pharmaceutical ingredients, finished products, materials intended for medical use, and drug containers, including identification and analysis of narcotics, illicit drugs, and psychotropic substances. The Bureau also establishes a national pharmacopeia, produces reference substances, and provides a proficiency testing scheme.
History	The laboratory has been regularly inspected by the WHO PQ Inspection Services. The last PQ inspection was conducted in November 2019.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: 1. Quality management system 2. Document control system 3. Calibration, qualification, and computerized system validation 4. Premises, reagents, and volumetric solutions 5. The physical, chemical, instrumentation, pharmaceutical, and narcotics laboratories. 6. The reference standards laboratory
Restrictions	None
Out of scope	The microbiology section and laboratories other than pharmaceutical laboratories were outside the scope of this inspection.
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	Nonconformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specification 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**

1. Organization and Management

The Bureau of Drug and Narcotic (BDN), Department of Medical Sciences (DMSC), is mainly responsible for testing pharmaceutical products. The laboratory director is overall responsible for establishing, implementing, and controlling an effective quality system and data governance. The laboratory has various policies, procedures, and instructions to ensure that the laboratory's objectives are met, including declaring conflict of interest by all staff members and not being subject to commercial, financial, and other pressures. The organization chart and responsibilities of the BDN staff are described and available in the quality manual. There are 7 Sections within the Bureau of Drug and Narcotics that reported directly to the Director:

- Chemical and Physical Testing Section
- Biological Testing Section
- Narcotic Section
- Quality and Technical Development Section
- Thai Pharmacopoeia Section
- Reference Standard Section
- Administrative Office

According to the organizational chart, the quality manager position reported directly to the director and was independent of the other sections.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

2. Quality management system

The Bureau's quality management system was according to ISO/ IEC 17025:2017 requirements and WHO good practices for pharmaceutical quality control laboratories. The quality manager (QM) reported directly to the Bureau director. The QM regularly communicates with all Bureau laboratories to identify and resolve quality assurance (QA) issues. The technical management team makes commitments to develop, implement, and continually improve the management system's effectiveness.

The **quality manual** was revised on 2 August 2024 (edition 17). It included a risk assessment section, revised responsibilities for the laboratory head and supervisor, cross-referencing the SOPs to clarify information management, and reviewing records. The QM was prepared based on the ISO 17025:2017 clauses and generally provided basic quality system requirements.

Management reviews were conducted per the SOP "Management Review" once per year. The most recent one was checked, covering the period from 01.10.2022 to 30.9.2023. According to the presented documents (meeting records), the management review meeting took place on 27.02.2024 and was attended by 22 people, including the Director, Quality Manager, and Heads of Sections.

The **change control procedure** was discussed. The procedure was prepared following the WHO TRS 1052 Annex-4. It provided a clear purpose and was applied to changes related to documents, analytical equipment, testing methods, reference standards, chemicals, reagents, utilities, facilities, computer software, computer firmware, policies, etc. The initiator used a change control form, which provided details about the change proposed by the initiator. A document review form was used to control document changes.

The **quality risk management** procedure provided a high-level description of facilities' risk management processes, and BDN referred to the DMSC procedure. Upon review of the procedure, it was noted that risk was calculated using impact and probability without considering detectability. Also, the procedure did not provide the use of various tools (except FMEA) required for carrying out an appropriate risk assessment. The procedure assigned risk priority numbers into green, yellow, and red categories equivalent to 1-6, 8-12, and 15-25. The BDN had a committee that assessed risks. The recent risk assessment related to the existing process was performed on 8th August 2024, and the RPN calculation was completed on 19th August 2024.

The **deviation handling** procedure was reviewed. It was noted that deviations were recorded as unplanned and categorized into minor and major deviations. A total of 61 unplanned deviations were raised in 2024. The laboratory also described these 61 unplanned deviations as non-conforming products and had a separate procedure for non-conforming products.

Complaints: According to the SOP "Procedure for Complaints and Appeals," the Quality and Technical Development Section handled complaints, while the Quality Manager approved them. According to the provided list, 18 complaints were registered in 2023.

Corrective action preventive action (CAPA): The SOP for Corrective and Preventive Actions (CAPA) has recently been revised. Several Quality Management System (QMS) elements previously required to initiate a CAPA were removed in the updated version.

The laboratory had developed a **business continuity plan** in 2023, available in Thai. The plan identified potential areas that could affect business continuity due to natural disasters. The plan also identified that servers and equipment were available in other laboratories, and work could be continued with the help of laboratories located in the region of Thailand. For the continuity of the power supply, the laboratory had its own generator, which supplied non-stop power.

The SOP for participation in the **proficiency testing (PT) scheme** (Pharmaceuticals) was discussed. The procedure was referenced to ISO/IEC 17043:2023. The quality manager was responsible for developing the annual PT plan, which was approved by the laboratory director. The procedure provided guidance on participation in the Proficiency Testing Scheme (PTS), including the reporting of results to the PT provider.. An action plan for participation in PTS, dated 7th March 2024, was available. This plan was prepared for the period Oct 2023- Dec 2024. Providers such as EDQM (UV-VIS, HPLC), WHO (pH, assay, related substances, dissolution, and disintegration), UNODC (international collaborative exercise for seized material and biological specimen), and LGC (sterility and residual solvents) were identified for the PTS.

According to the SOP "**Internal Audit**", an internal audit was conducted at least once a year. The SOP stated that compliance with ISO 17025:2017, ISO 9001:2015, and WHO GPPQCL should be verified during the audit. Audit reports were approved by the Quality Manager and distributed by the Quality and Technical Development Section. The results of the internal audits were considered during the Management Review. According to the SOP, audits were planned for all areas from March to April each year. The audit plan for 2024 was reviewed. The plan was approved by the Quality Manager and the Director on 21.02.2024.

Supplier qualification was conducted per the "Externally Provided Products and Services" procedure. Because BDN is a public laboratory (under the Ministry of Public Health), national law regarding procurement by public entities applies. A special-order form was used to order from a list of approved suppliers.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

3. Control of documentation

All quality system documents were managed according to an established procedure to ensure control, protection, and proper storage. Defined processes were in place for the receipt, review, and release of documents. Within the quality management system, documents were classified into five hierarchical levels:

- Level 1 Quality Manual
- Level 2 Standard Operating Procedure (SOP), Quality Procedure (QP), Work Instruction
- Level 3 worksheet, form, logbook
- Level 4 supporting document

- Level 5 other quality-related document e.g., quality management plan, laboratory information file, protocol, report of validation/verification method

The documentation was signed on paper, while employees accessed it electronically after logging in. Documents were available on the intranet, and the Quality and Technical Development section ensured their accuracy. Every employee with intranet access had access to the latest versions of all documents.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

4. Records

The procedure for the control of records was available in Thai. The procedure stipulated requirements for maintaining records by uniquely identifying and accessing, backing up, and maintaining both paper and electronic records. The laboratory informed that the records were retained for 5 years.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

5. Data processing equipment

The SOP on control of data and information management was reviewed. It was noted that the procedure was in Thai and provided guidance about data collection, access, retrieval, security, and disposal. Another SOP, titled "Back-Up Records in Electronic Data," stipulated requirements for backup and restoration. The SOP on Good Data and Record Management Practices was discussed. The laboratory has been using several equipment and instruments connected to computerized systems. The SOP on computer user policy was reviewed. It noted only two user levels (administrator and user). It stated that users must protect their own passwords and that they should have at least four letters. The procedure also stated that the administrator should have complete access and can add or remove any program to change system settings. It also stated that users cannot change or delete files or folders.

A list of validated computer systems for analytical instruments was available, providing information about the instrument's name, brand name, model name, firmware, Windows, drive path, instrument number, responsible person, calibration status, section, and location. It was noted that the computer systems were validated as part of the calibration performed by the equipment supplier. The supplier validated the computerized system as part of the qualification for the respective equipment.

A general procedure for chromatography was reviewed. This procedure provided general guidance on chromatography. It was last revised in 2012 and appeared not to be in regular use. Also, the procedure did not have information on appropriate integration management. During the visit to the laboratory, it was found that manual integration was exercised.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

6. Personnel

Number of employees engaged in the following activities:

Activity	Number
Supervisors	15
Chemical sector	
Analysts	28
Microbiological sector	
Microbiologists	18
Narcotic sector	
Analysts	22
Reference standard sector	
Analysts	9
Quality assurance staff	5
Other	42
Total number of employees in the laboratory	139

The following job descriptions were verified:

- Quality Manager dated 10.04.2023.
- Head of Chemical and Physical Testing Section dated 26.01.2024.
- Head of Narcotic Section dated 15.03.2024.
- Head of Quality and Technical Development Section dated 12.12.2023.

“Training Procedure" describes the approach to employee training. According to the SOP, each employee underwent general training (e.g., responsibilities of the Bureau, ISO Quality System, laboratory procedures, laboratory safety, handling chemicals and waste management, standards, glassware, preparation of standards) as well as specialized training related to specific job positions (e.g. uniformity of dosage, content uniformity, dissolution). The employees of BDN were trained on an ongoing basis according to the training plan. The training record of the Chemical and Physical Testing Laboratory employee, an internal auditor, was reviewed.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

7. Premises

The Bureau has two buildings with approximately laboratory space and office areas as follows:

- Laboratory area: 4,400 square meters
- Office areas: 1,500 square meters

The Bureau occupies two buildings; building no. 2 has six stories, and building no. 4 has three stories. These two buildings accommodated 12 laboratories. The inspectors visited the sample receipt, storage, and retention sample areas on the 4th floor. Then, they visited the pharmaceutical laboratory on the 3rd floor, where HPLC analysis was performed. The inspectors also visited the 2nd floor, where chemicals (liquid and solid) were stored.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

8. Equipment, instruments, and other devices

The equipment and instruments used for analysis were tested for performance to ensure they met the ISO/IEC 17025:2017 and WHO GPPQCL requirements. The suppliers calibrated, qualified, and maintained the equipment, instruments, and devices. The analytical balances were verified daily, whereas most equipment, instruments, and devices were calibrated once every 6 to 12 months.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

9. Contracts

BDN's policy does not allow subcontracting the analytical work within the scope of accreditation.

10. Reagents

The preparation of solutions, including volumetric solutions, was described in SOP "Preparation of solution in the chemical Laboratory ". According to the SOP, the concentration of the volumetric solution was indicated in terms of normality or molarity. The process of preparation by weighing, dilution, and standardization was described. Volumetric solutions were standardized using the methods described in the Pharmacopoeia.

Most volumetric solutions were prepared on an as-needed basis and were not stored. During the site visit (Chemical and Physical Testing Laboratory 2), a 2M NaOH volumetric solution was checked. Records from the preparation dated 11.07.2024 and the labelling of the container with the volumetric solution were reviewed. The raw data were consistent. The label included all required information, including the preparation and expiration dates of the 2M NaOH, 11.07.2024 - 11.01.2025.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

11. Reference substances and reference materials

The BDN was responsible for preparing and standardizing reference standards for in-house use and supplying them to various clients, including the pharmaceutical industry within and outside Thailand. The laboratory was equipped with refrigerators and freezers. It was noted during the visit to the reference standards laboratory that refrigerators, freezers, and walk-in chambers were not adequately maintained. There was no confirmation if temperature mapping was performed to determine the worst-case scenario, including the alarm challenge test. The temperature data from the computer system was not reviewed to ensure predefined conditions were met. The laboratory could not demonstrate temperature data for January-May 2024 when requested.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

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

The laboratory had equipment and instruments such as HPLC, UPLC, GC, UV-VIS, FTIR, etc. The equipment and instruments were used to analyze pharmaceutical products, microbiology testing of herbal products, ATMPs, and other products. The calibration frequency for all this equipment and instruments was kept the same. The suppliers of the respective equipment and instruments performed the calibration and maintenance of the equipment and instruments. The equipment and instruments were purchased through a tender process, whereas calibration and maintenance activities were outsourced to suppliers under an annual contract. The suppliers carried out the calibration and maintenance using their own protocols. The report was shared with the laboratory after the calibration and maintenance activities were completed.

An annual calibration schedule for the fiscal year was available, stating details of the name & brand of the equipment, serial number, the frequency for calibration (6 or 12 monthly), the person responsible, the name of the lab, etc. The schedule also provided a column for remarks/comments when calibration was not performed due to COVID-19 or equipment breakdown. The laboratory has qualification documents for dissolution, HPLC, GC, and other equipment. In addition, it has standard operating procedures for specific equipment and instruments.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

13. Traceability

The traceability was ensured from the samples' receipt to the completion of the testing. The respective records were available to ensure the traceability of the results reported to various clients. Traceability was also ensured through reference standards, HPLC columns, reagents, etc. The obsolete documents were retained to confirm traceability.

14. Incoming samples

The sample receipt form contained basic information (such as the purpose of the analysis) about the incoming sample before it was accepted for analysis. A separate sample receipt form/letter was used for the samples received from the Thai FDA. The barcode labels were printed using iLab software developed by the DMSC. The retention samples were also stored in different cabinets in the same room for 1 year. After one year, either the samples were destroyed or returned. Upon logging the incoming samples, the sample custodian split the samples into different parts for physical, chemical, and microbiology analysis and handed them over to the head of the laboratory.

The inspectors then visited the pharmaceutical laboratory on the 3rd floor, which is equipped with 6 HPLC systems. They verified calibration, analysis, and integration-related checks on various HPLC systems. The logbook was maintained for each HPLC column, which was calibrated upon receipt.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

15. Analytical worksheet

Analytical worksheets were supervised per the SOP for 'Document Control.' After logging into the system, analysts could access the worksheets. The Quality and Technical Development Section was responsible for entering the current versions into the system. Raw data was entered manually. The data for the 'Content Uniformity HPLC' test for the product was reviewed. The test was conducted according to the 'Content Uniformity HPLC" No. N25-02-01. The test was completed on 23.03.3024. Records were kept appropriately, and the documents were signed by the Analyst and the Head of the Laboratory.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

16. Validation of analytical procedures

The SOP for method validation of chromatographic methods was reviewed and prepared based on the ICH, USP, and Lab compliance guidelines. The SOP referenced an obsolete WHO validation guideline and the EDQM. The procedure stated that the new analytical method, including the change in the method, would trigger validation. The procedure described a list of parameters, including their acceptance criteria. The laboratory confirmed that most of the analytical methods were verified. A list of the methods was available. It was noted that the laboratory validated and verified the chromatographic analytical methods. The procedure was available in Thai and appeared to be adequate.

A separate procedure, "Verification of chemical methods," was discussed. The procedure stated that analytical methods from the International Pharmacopeia, BP, EP, USP, Thai Pharmacopeia, and Thai Herbal Pharmacopeia would be verified. The procedure listed parameters such as specificity, precision (repeatability and limit of quantitation), accuracy, filter effect, and stability of the solution that would be performed to verify methods. The procedure was available in Thai and appeared to be adequate.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

17. Testing

Sample No. 6 was tested for Pyrazinamide identification using a UV/VIS Spectrometer model Lambada in Room 433 at the Chemical and Physical Testing Laboratory 2 on 16.07.2024. The raw data from the test were reviewed. All records, raw data, and calculations were found to be correct. The documents were duly signed. Furthermore, the 'Content Uniformity HPLC' test data was reviewed.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

18. Evaluation of test results

The Out of Specification (OOS) was discussed. The SOP was recently revised in July 2024 after adding details of the reviewer and the approver. The OOS was investigated in two phases (phase one was done using a checklist, and phase two was investigated in more detail in the lab). The procedure also stated hypothesis testing and retesting in triplicate. Hypothesis testing was usually required in the phase one stage, not in the phase two stage, as noted from the flow diagram. Also, original solutions should not be discarded until the investigation is completed.

In 2024, the laboratory raised 106 OOS (related to chemical and microbiology from pharmaceuticals and herbal products). In 2023, 97 OOS were raised (mostly related to microbial limit tests, assays, and other tests). As part of the management review, the laboratory compiled these OOSs in a tabular form listing the number of valid and invalid tests (MLT, assay, elemental analysis, etc.).

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

19. Certificate of analysis

The laboratory did not issue a Certificate of Analysis. According to the SOP, the “Report of Analysis”, the document - Report of Analysis was the final document presenting the obtained results, signed by the Director and sent to the client. There was no signature from the Quality Manager on this document.

The 'Report of Analysis' for the medicinal product (for children) was reviewed. The report was approved by the Director on 13.08.2024. The Analyst and the Head of the Laboratory signed the test results on 13.08.2024. The Thai FDA sent the product for testing to analyze sulfamethoxazole and trimethoprim content and dissolution, with a cover letter.

20. Retained samples

Retained samples were stored in the same room where incoming samples were received and stored. The laboratory has a policy of retaining these samples for one year. If the senders did not retrieve the samples, they were disposed of after one year.

21. Safety

The laboratory had eye wash, safety showers, and fire extinguishers.

The deficiencies raised in this section were adequately addressed and will be verified during future PQ inspections.

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, **the Bureau of Drug & Narcotic**, located at **the Department of Medical Sciences, Ministry of Public Health, 88/7 Tiwanond Road, Muang Nonthaburi, 11000, Thailand**, 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. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052, Annex 4. ***Short name: WHO TRS No. 1052, Annex 4*** https://www.who.int/publications/m/item/who-good-practices-for-pharmaceutical-quality-control-laboratories

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 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

4. 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

5. 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

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. 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 961, 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

8. 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

9. 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

10. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3. ***Short name: WHO TRS 1033, Annex 3***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

11. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS 1033, Annex 4*** https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations