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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Pharmaceutical Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Micro Labs Limited, Kumbalgodu (ML08)**
Corporate address of the manufacturer	Micro Labs Limited #31, Race Course Road, Bangalore – 560 001. INDIA. Tel.: +91 (080) – 22370451 to 57 Fax: +91 (080) – 22370463
Name & address of inspected manufacturing site if different from that given above	Plot No. 15/A, 2nd Phase, Kumbalgodu Industrial Area, Bangalore – 560074, India. D-U-N-S (Data Universal Numbering System) number (a unique identification number provided by Dun & Bradstreet) of the site is 91-583-9982
Unit/block/workshop number	ML08
Inspection details	
Dates of inspection	18-21 February 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Micro Labs Limited (ML 08) is located at 15/A, 2nd phase, Kumbalgodu Industrial Area, Bangalore, Karnataka, India. The site manufactured several dosage forms as outlined below. Only the manufacture of the oral solid dosage forms for human consumption (specifically, WHO prequalified products) was inspected
General information about the company and site	Micro Labs was established in 1973. The company manufactures medications for various therapeutic applications, including cardiovascular, psychotropic, neurological, anti-diabetic, gynecological, gastroenterological, dermatological, antibiotics, and ophthalmic products. It has 15 manufacturing facilities that produce products for both domestic and export markets.
History	This was Micro Labs ML08's routine GMP inspection. WHO last inspected the site in August 2022 after the renovation.

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Pharmaceutical quality system - Personnel, hygiene, and training - Equipment, instrument qualification, maintenance, and calibration - Production and packaging operations - Warehouse and material management - Quality control laboratory, including microbiology section
Restrictions	None
Out of scope	The products and areas outside the scope of the WHO PQ were not inspected.
WHO products covered by the inspection	1. Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol HCl tablets (4FDC) (TB223) 2. Linezolid 600mg tablets (TB323) (transferred to ML03) 3. Pyrazinamide 150mg dispersible tablets (TB335) (transferred to ML03) 4. Isoniazid 50mg dispersible tablets (TB347) (transferred to ML03) 5. Isoniazid 100mg dispersible tablets (TB348) (transferred to ML03) 6. Ethionamide 125mg dispersible tablets (TB352) (no commercial supply from ML08) 7. Trimethoprim and Sulfamethoxazole tablets (HA598) 8. Trimethoprim and Sulfamethoxazole tablets (HA599) **Note:** The company informed that thirteen (13) batches of 4FDC (TB223) were produced in 2024 and four (4) in 2025. No batches of HA599 were produced in 2024 and 2025, whereas 146 batches of HA598 were manufactured in 2023 and 1 batch in 2024.
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original, and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices

GPT	Growth promotion test
HEPA	High-efficiency particulate air
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation, and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
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
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

Part 2	Summary of the findings and comments

1. Pharmaceutical quality system

A documented system for quality assurance was established, with procedures in place that cover key quality elements. The quality control department and production department were independent of each other with separate reporting lines. Operations were specified in written form, and critical GMP requirements were essentially met. Corporate quality assurance (CQA) provided guidance and procedures for all Micro Labs manufacturing units. The site uses the following software:

- DMS (for the procedure, specifications) and batch manufacturing records were issued through SAP.
- LIMS (for laboratory operations, which is not interfaced with TrackWise)
- TrackWise for quality system elements
- Nichelon 5 CMS for training management system

The following PQS elements were reviewed:

Product quality review (PQR)

The SOP for PQR was discussed. The PQR plan for Jan-Dec 2024, which stated three WHO PQ products, was identified for review. The review was completed on 17/02/2025. The PQR plan for Jan-Dec 2023 was available and was completed by March 2024. The process capability (CpK) was calculated using Minitab software, and a minimum of 30 batches was required for the calculation. If fewer than 30 batches were manufactured, data from the previous year would be used in its place. A graphical summary and an I-chart were performed for the data of a minimum of 10 batches. A Line plot was prepared if fewer than 10 batches were manufactured. If an I-chart was prepared, a line plot was not applicable. The PQR of 4FDC (TB223) for Jan-Dec 2024 was reviewed.

Change control

The corporate procedure "Change Control System" governed the management of changes. Similar to deviations, major and critical changes required approval at the corporate level by the CQA Head. Changes were managed using the TrackWise system. In 2023, a total of 111 changes were recorded, including 40 major and 71 minor changes. In 2024, the number increased to 167 changes, comprising 55 major and 108 minor changes. The change related to the introduction of new equipment, a double rotary compression machine (65 station), manufactured by Parle Elizabeth Tools Pvt. Ltd was reviewed. As it was classified as a major change, corporate approval was granted on 18/11/2023. The change was closed on 09/01/2024 after the completion of the equipment qualification. The change CCR-MLO8-2024-0156, dated 21/12/2024, was reviewed. It involved introducing a new cleaning system for supply ducts and adding extra cleaning components to the exhaust ducts for both the Fluid Bed Dryers (EM-002 & EM-011) and the Coating Machine (EM-030).

Deviation

The procedure "Handling of Deviations" described the process for managing deviations. The manufacturer classified deviations as minor, major, or critical. The head of QA (at the site) approved all classifications and action plans. In cases where major or critical deviations occurred, additional approval at the corporate level was required from the Head of Corporate QA. In 2023, 25 deviations were recorded, including 16 major and 9 minor. In 2024, the number of deviations reached 21, comprising 14 major and seven minor. At the time of the inspection, four (4) deviations were identified – two (2) major and two (2) minor.

CAPA

The SOP "Handling of Corrective and Preventive Actions" covered various activities, including those resulting from the handling of deviations, self-inspections, OOS and OOT investigations, change control, and deficiencies identified during audits and inspections. CAPA was managed in the Track Wise system.

Quality risk management (QRM)

The SOP for QRM provided instructions for assessing risks throughout the product life cycle. The risk assessment was carried out reactively and proactively. An annual risk assessment planner for 2025 was prepared, and five areas of risk assessment were identified (contamination and cross-contamination, manufacturing and packing process, laboratory control and stability management, equipment preventive maintenance program, and material management). In 2024, nine (9) risk assessments were performed, covering backup and restoration of data, environmental monitoring systems, change control, and other relevant areas.

The SOP for batch release was discussed. It was noted that the procedure has been recently revised to include verification of variation approval, ongoing stability checks before release/dispatch, and other amendments. The head of the site QA was responsible for releasing batches; two QA personnel were authorized to release batches in the QA Head's absence. A batch release was performed using checklists, including a review of BMR, BPR, and analytical reports. The audit trails related to QC equipment were reviewed by the QC and Analytical QA (AQA). Out of 6 batches manufactured in 2024, the company recalled four, which were supplied to UNOP, and the other two were supplied to the rest of the world (RoW) markets. In 2024, 14 batches (13 batches of 4FDC and one batch of HA598) were manufactured and released.

Management Review

According to the SOP "Management Review," the management review consisted of the following stages:

- Level 1 – Production and Facility Review,
- Level 2 – Quality System Review,
- Level 3 – Site Management Review,
- Level 4 – Senior Management Review.

The Level 1 and Level 2 reviews were conducted at the manufacturing site, whereas Level 3 and Level 4 reviews were carried out at the corporate level. The meetings at the manufacturing site were attended by employees working at that location. In contrast, the Operational Head and Head of Site QA representatives attended the corporate-level meetings as representatives of the manufacturing site. The data from the Level 1 and Level 2 reviews were sent to the corporate level for further analysis. Meeting minutes were prepared for each of the meetings mentioned above. These minutes were available to employees and were presented during the inspection.

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

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources, including adequate premises, equipment, and utilities, were provided to support the current operational level of various finished pharmaceutical products. The manufacturing processes followed procedures as defined and documented in the BMRs. The personnel were appropriately qualified. The manufacturing facility where Rifampicin products were handled was separated from the non-Rifampicin products. The ML08 was renovated in 2019 and became operational in 2021. Since then, the site has manufactured two products (4FDC and Trimethoprim/Sulfamethoxazole tablets).

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

3. Sanitation and hygiene

Clean areas were frequently disinfected per the defined process and procedure. More than one type of disinfecting agent was used. The hygiene facilities established on the site appeared acceptable.

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

4. Qualification and validation

The cleaning validation procedure was discussed. Equipment cleaning was performed using potable water, a 0.1% Teepol solution, and a final rinse with purified water. The worst case was determined using the solubility of the API, PDE value, minimum therapeutic dose, and product strength. The procedure also described the equipment group matrix and the determination of maximum allowable carryover and acceptance criteria, including dose criteria (10 ppm) and PDE value. The toxicologist registered as a Diplomate of the American Board of Toxicology (DABT) or a European Registered Toxicologist signed the PDE reports.

The analytical method validation protocol and report for Rifampicin, Isoniazid, and Pyrazinamide dispersible tablets were reviewed, and it was noted that the method was validated at the company's R&D facility in Mumbai, India. The validation included tests such as selectivity, forced degradation, system precision, method precision, intermediate precision, linearity, the limit of detection, the limit of quantitation, accuracy, recovery, range, solution stability, robustness, system suitability, and filter paper interference. The related substance method was validated, covering Rifampicin, Isoniazid, and Pyrazinamide, whereas no related substance test was required for Ethambutol HCl. It was noted that a separate AMV was not performed for 4FDC; however, some tests, including solution stability, filter interference, robustness, specificity, and precision, were conducted for 4FDC in 2013. AMV-related substance Method 1 of Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol tablets (AMVP/ML08/FP/18/005 dated 03/05/2018) was performed on-site in 2018.

Process validation:
The process validation procedure provided instructions for conducting process validation and continued process verification, and applied to all manufacturing and packaging validation. The procedure described that at least three batches should be manufactured as part of the process validation for stages 1 and 2. The procedure also described how packing validation would be performed for blister packs. However, no details were provided for strip packing and bottle packing. Minitab was used for the continued process verification, wherein CPPs and CQAs were consolidated and presented in a graphical (control chart) presentation.

Computer system validation
The computerized system validation procedure was reviewed, and it was noted that the procedure was developed in accordance with the CFR, ISPE guidelines, and other relevant standards. The obsolete version of WHO TRS 937 was referred to in the procedure. The systems were periodically reviewed using the GAMP category (COTS-as-is, configurable COTS, and customized software) and a risk-based approach (max 5 years and min 1 year). The inventory of computerized systems dated 01/01/2025 was available, stating the software names, system/instrument ID, software version, last validated, due for the next review, etc. Additionally, a separate inventory list was maintained for enterprise applications, including TrackWise and LIMS.

Qualification of HVAC
According to the "Qualification of HVAC System", the qualification scope included:

- Air velocity and total air flow rate of Fresh Air in CFM
- Number of air changes per hour in the area
- Filter integrity test for HEPA filter
- Non-viable airborne particle count
- Area recovery test
- Airflow pattern/visualization test

A review of 12 months of environmental monitoring results using settle plates and volumetric air samples was also conducted.

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

5. Complaints

The SOP for handling market complaints was reviewed. The procedure also described how the Pharmacovigilance department provides input on the safety aspects. As such, there was no confirmation of how the complainant provided feedback about the product. The company has not received any complaints in 2023, 2024, or 2025 (as of now). The corporate QA handled the product recall procedure for the export market. Before initiating a recall, the corporate QA sought feedback from the respective site.

6. Product recalls

The product recall procedure was in place. Due to time constraints, it was not reviewed in detail.

7. Contract production, analysis, and other activities

According to the SOP “Approval of Contract Laboratories for Testing”, the procedure for approving contract laboratories was conducted at the corporate level. The frequency of audits in contract laboratories was once every two years. The "List of Certified Contract Testing Laboratories", approved on 17/01/2025, was presented. The list included nine contract laboratories.

8. Self-inspection, quality audits and suppliers’ audits, and approval

The topics related to self-inspections were covered by the SOP “Self-Inspection”. According to this SOP, six audits were conducted annually in the following areas: Quality System, Facility and Equipment System, Laboratory System, Packaging and Labelling System, Production System, and Material System. The procedure also specified the criteria for selecting auditors, including qualifications in a scientific or pharmaceutical discipline and a minimum of four years of work experience. There were 12 approved auditors. Based on their experience, each auditor on the list was authorized to inspect specific areas of the facility. The Head of QA was responsible for preparing the annual self-inspection plan.

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

9. Personnel

The site employed 125 technical staff and utilized contract staff and temporary workers for primary packaging and other activities. It was noted that the site employs 2 IT operators, who report to the site’s VP of Operations.

The corporate procedure "Quality Assurance Procedure" covered, among other things, the preparation of the organizational chart and the assignment of responsibilities. According to the approved organizational chart, Quality Control and Quality Assurance were independent of Production. Furthermore, the unit head and senior GM of production reported to the senior vice president of operations on-site. In contrast, the QA Head and QC Head report directly to the Vice President, Corporate Quality.

The job descriptions of key personnel were reviewed and found adequate.

10. Training

According to the SOP "Training of Personnel," training sessions included initial, periodic, CAPA-related, and other types of training. Periodic training sessions were included in the annual training plan and were required to be completed by every employee (except contract workers). The training sessions were conducted according to the plan, approved by the Head QA. Each month, one periodic training session was prepared and conducted in groups of approximately 20 employees (it was repeated about six times).

11. Personal hygiene

The SOP "Personnel Hygiene" applied to all personnel. This procedure outlines the main hygiene principles, including medical examinations for personnel and the use of personal protective garments. Detailed requirements in this regard were specified in the procedures listed below. According to SOP "Medical Checkup", all personnel underwent an annual medical check-up. This procedure was applied to all employees and specified the scope of the mandatory medical examination. The SOP "Entry and Exit Procedure for Receiving Bay, Manufacturing, Primary Packing, Sampling, and Dispensing Areas" specified the appropriate garments for Class D and non-classified areas. Red protective garments were used in all Class D areas. For areas related to the manufacturing of Rifampicin, dedicated protective garments, differing in shade of red, were required. In non-classified rooms, white garments were used. The garment segregation system was implemented in the room dedicated to Rifampicin and multi-product rooms. All garments were washed separately in the laundry facility and manufacturing site (in a different building).

12. Premises

This manufacturing facility (ML08) was commissioned in 2005. It was renovated in 2019 and became operational in August 2021. The details of the built-up area are as follows:

Processing Area	1150 sq. meters
Packing Area	675 sq. meters
Warehouse	1100 sq. meters
Service Area	2100 sq. meters
Ancillary Area	1200 sq. meters
Quality Control	575 sq. meters
Utility / Engineering	1050 sq. meters
Total	7850 sq. meter

The facility was vertically designed. The ground floor was used to store incoming starting materials and carry out primary and secondary packaging activities. The first floor was used for manufacturing activities, containing two granulation suites, blenders, compression machines, and a coater. The manufacturing areas were classified as Grade D (Class 100,000, ISO 8), and temperature (NMT 25°C) and relative humidity (NMT 40% and NMT 60% in certain areas) were maintained.

Water system

Raw water was received via tankers and treated using a reverse osmosis skid to produce potable water, which was then further purified through ultrafiltration. A quick visit to the water system noted there was no leakage. The online SCADA system monitored the flow, conductivity, and TOC, and 16 distribution loops or user points were identified. The water system did not have double-pass RO and

EDI. Sanitization was performed once every 15 days using purified water at 80°C for 1 hour. An auto-dumping system was in place to discharge the water if the conductivity or TOC exceeded the specified limits. The alert and action limits were defined.

Air handling units (AHUs)
AHU-36, which supplied air to the material dispensing areas, was briefly inspected. The AHU was equipped with fresh air, a 10-µm prefilter, and a 3-µm fine filter before the air passed through the HEPA filter, which was mounted terminally. The pressure across the filters was monitored and recorded. The filters were cleaned using potable water and compressed air in the filter cleaning booth.

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

13. Equipment
The manufacturing areas, quality control laboratories, and utilities were well-equipped with sophisticated equipment and instruments. Close equipment were used where possible to minimize the potential risk of contamination and cross-contamination.

14. Materials
The SOP for vendor approval outlines the procedure for approving vendors for new materials intended for commercial use. For API manufacturers, a questionnaire was followed by an on-site audit, whereas for excipient manufacturers, a risk-based approach was employed. The excipients were classified into three categories: high-, medium-, and low-risk. The procedure also stated that a vendor audit would be performed before the product's commercialization for the WHO, the US, Russia, the TGA, Canada, and other markets. The audits were performed for 3 years or less based on the risk factors. Similarly, for the excipients, high- and medium-risk excipients were audited for 3 years or less, but not more than 5 years, based on risk factors. For primary packaging materials, manufacturers were audited every three years.

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

15. Documentation
The oversight and documentation system was outlined in the procedure "Design and Control of Documents". According to this document, procedures were approved by the CQ Head, while the QA Head approved procedures prepared at the manufacturing site. The manufacturer had an established system for numbering procedures. Corporate procedures followed the same numbering format as those issued at the manufacturing site, but different symbols were used to distinguish them. The last number in the procedure's number represented the revision number. A procedure review was conducted every two years. The manufacturer reviewed all procedures verified during the inspection as required. The user department was responsible for reviewing procedures, and approval by QA was required. Procedures were managed electronically in the Caliber DMS system. QA oversaw the printing, distribution, and withdrawal of paper copies ("uncontrolled copy" and "controlled copy").

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

16. Good practices in production

The inspectors visited the production areas through the visitors' changing room. The first change room had a hand-wash facility, gowns, shoe covers, and a hairnet. The second change room on the first floor was equipped with a face mask, uniform, and footwear, among other items. The dispensing of red and white materials was carried out separately, and the dispensing room was equipped with separate MAL and PAL. The dispensing was performed by warehouse personnel and monitored by the QA. The production personnel verified the weight of the dispensed materials before charging. The temperature and relative humidity were maintained at 25 °C and 40%, respectively. The differential pressure between the secondary change room and process corridor was maintained at -2.5 mm WC. The environmental monitoring system was used to monitor temperature, relative humidity, and differential pressure. The production facility features two granulation areas equipped with granulators, a sifter, a multi-mill, a fluid bed dryer (FBD), and a bag dump station, among other equipment. The dispensed materials were charged into the granulator, FBD, and blender using a vacuum transfer system. The blender room was equipped with a separate MAL/PAL. A similar case was the second granulation section. Granulation I was used for Pyrazinamide and Ethambutol, whereas granulation II was used for Isoniazid. The compression machine I used for 4FDC was a 37-station machine, D tooling, single rotary, and equipped with a metal detector and dust collector. The primary and secondary packaging areas were located on the ground floor, and bulk tablets were received from the first floor via a common lift used for materials and personnel. The area had a bulk product store and a primary packaging material day store. At the time of the inspection, no packing activities were ongoing.

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

17. Good practices in quality control

The quality control laboratory was equipped with HPLC, GC, FTIR, UV-VIS spectrometers, a dissolution tester, analytical balances, and other instruments. Analytical quality assurance (AQA) ensured the quality of laboratory activities by reviewing various laboratory systems. The inspector visited the stability study chambers, retention samples, and QA documentation areas. The area had five chambers (25ºC/60%, 30ºC/65%, 30ºC/75%, 40ºC/75%, and a standby chamber for any condition). The annual stability study was performed for 4FDC and TMP/Sulfa products. The temperature mapping and calibration were carried out by the outside party once every year. The alarms were challenged during the preventive maintenance program. The alarm was available on-site, in the QC, and the service area, and the message was received through email. The chambers had a user ID and password, and Newtronics ICDAS2.1 was used. The samples were managed through LIMS.

The retention sample room was divided into two small rooms for storing samples below 25ºC (for 4FDC) and below 30ºC (for Trimethoprim/Sulfamethoxazole). The temperature was maintained using an air conditioner, and temperature mapping was performed as informed by the QA.

The SOP for handling OOS applied to raw materials, finished products, stability samples, in-process samples, etc.

The SOP for handling laboratory incidents described the procedure for handling incidents due to unusual/unexpected occurrences during testing samples, and did not lead to OOS/OOT. The incidents were handled through TrackWise.

The deficiencies raised in this section have been 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, ***Micro Labs Limited, Kumbalgodu (ML08)***, located at ***Plot No 15/A, 2nd Phase, Kumbalgodu Industrial Area, Bangalore, 560074, India*** was considered to be operating at an acceptable level of compliance with WHO GMP 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 manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
   untitled (digicollections.net)

3. 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 No. 1033, Annex 3
   9789240020900-eng.pdf (who.int)

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
   https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile 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 8. **Short name: WHO TRS No. 1010, Annex 8**
   https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

6. 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
https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

7. 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 TRS No. 961, 957), Annex 1
https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
Short name: WHO TRS No. 961, Annex 6
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

10. 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
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9***
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

12. 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***
https://digicollections.net/medicinedocs/#d/s21438en

13. 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
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.

Short name: WHO TRS No. 981, Annex 2
https://digicollections.net/medicinedocs/#d/s20177en/

15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
https://digicollections.net/medicinedocs/#d/s20175en/

16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

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