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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Anuh Pharma Ltd**
Corporate address of manufacturer	3-A Shivesagar Estate, North Wing, Dr. Annie Besant Road, Worli, Mumbai-400018 India.
Inspected site	
Name & address of inspected manufacturing site	E17/3 & 17/4 & E-18 MIDC, Boisar Tarapur Taluka-Palghar, Thane District, Maharashtra 401 506, India Latitude: N 19° 48' 6" Longitude: E 72° 44' 3" DUNS No.: 915041156
Unit / block / workshop number	The following blocks/areas were covered during the inspection: → AB-3 manufacturing block within APL1 building of E-17 construction. → NP-1 manufacturing block within APL2 building of E-17 construction. → API-II manufacturing block (and the associated intermediate block 2A [Int-2A]) of E-18 construction. → Raw and packaging materials warehouses at E17 and E18. → Finished API and intermediates warehouse at building of E-18 construction. → Quality control laboratories including microbiological laboratory at the building of E-17 construction.
Inspection details	
Dates of inspection	10 – 12 June 2024
Type of inspection	Routine on-site inspection
Introduction	
Brief description of the manufacturing activities	The site was authorized for manufacture, including production and control of API and intermediates, along with storage and distribution activities. The site consisted of 3 manufacturing buildings, namely APL1, APL2 and E-18. APL1 and APL2 were connected to each other and were housed within one single construction (collectively referred to as E17). APL1 and APL2 were subject to earlier WHO inspections (jointly conducted with the European Directorate for Quality of Medicines [EDQM]) in 2016 and 2018. On the other hand, E18 was a standalone building with a construction separate from E17. E18 was built in 2019 and became operational in 2020 so it was not subject to any WHO inspection in the past. APL1 comprised 2 manufacturing blocks (AB-3 and AB4) along with 2 dedicated air jet milling rooms, one blending room, quality control (QC) and microbiology Departments. APL2 comprised 4 manufacturing blocks (NP-1,NP-2,NP-3 and NP-4) along with dedicated raw and packing material warehouse at the basement. E-18 comprised 1 intermediate block, and 2 API blocks (API–1 and API–2). It also comprised the administration area, training room, quality assurance office and

<table>
<tr><td></td><td>intermediate and finished products warehouse. E18 also included areas for storage and dispensing of packaging materials.
All WHO prequalified products were produced at E17 with the exception of sulfadoxine which was additionally produced at E18. The following table summarizes the location where WHO products were produced.
<table>
<tr><th>Name of product</th><th>PQ number</th><th>Manufacturing block</th></tr>
<tr><td>Sulfadoxine</td><td>WHOAPI–234</td><td>AB-3 (E-17) and API-II (E-18)</td></tr>
<tr><td>Pyrimethamine</td><td>WHOAPI–364</td><td>AB-3 (E-17)</td></tr>
<tr><td>Pyrazinamide</td><td>WHOAPI–158</td><td>NP-1 (E-17)</td></tr>
<tr><td>Isoniazid</td><td>WHOAPI–418</td><td>NP-1 (E-17)</td></tr>
</table></td></tr>
<tr><td>General information about the company and site</td><td>Anuh Pharma Limited (APL) is a manufacturer of active pharmaceutical ingredients (APIs), which was founded in 1960. The production at the current site was started in 1989. Anuh Pharma is a public limited company listed on Mumbai stock exchange. It is part of SK Group, which in turn was established in 1932. APL is one of the largest manufacturers of macrolides and anti-TB products in India, besides being a major player in anti-bacterial, anti-malarial, anti-diabetic, anti-hypertensive and beta-blocker active ingredients. The corporate office of APL is based in Worli, Mumbai, while the manufacturing site (subject to this inspection) is located in Boisar, Tarapur within the Maharashtra Industrial Development Corporation (MIDC) area in Maharashtra state at about 75 miles north of Mumbai.</td></tr>
<tr><td>History</td><td>The site was subject to the following inspections:
→ Regular inspections by Indian authorities (FDA Maharashtra State and CDSCO)
→ US/FDA in September 2019
→ WHO-EDQM-AEMPS joint inspection in November 2018
→ WHO-EDQM-ANSM joint inspection in September 2016
→ EDQM-ANSM inspection in February 2016</td></tr>
<tr><td colspan="2">Brief report of inspection activities undertaken Scope and limitations</td></tr>
<tr><td>Areas inspected</td><td>Pharmaceutical Quality System
Documentation
Facilities and Equipment (warehouses, workshops)
Utilities
Production
Packaging and labelling
Product Release
Quality Control laboratories</td></tr>
<tr><td>Restrictions</td><td>The inspection was restricted to the manufacturing of the products listed in the inspection scope. Other products and production areas/lines were not covered by this inspection.</td></tr>
<tr><td>Out of scope</td><td>APIs not submitted for WHO Prequalification were excluded from the scope of this inspection. In addition, blocks and areas not listed under the “Inspected Site” were not covered during the inspection and as such are out of the scope of this report.</td></tr>
<tr><td>WHO products numbers covered by the inspection</td><td>→ Pyrimethamine, WHOAPI-364b, APIMF 364b
→ Isoniazid, WHOAPI-418, APIMF 418
→ Pyrazinamide WHOAPI-158, APIMF 158
→ Sulfadoxine WHOAPI-234, APIMF 234</td></tr>
</table>

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
NCA	National control authority
NCL	National control laboratory
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 (where applicable)**

1. Pharmaceutical quality system

Principles, quality manual (QM) and quality policy (QP)

The company presented its QMS, which described the principles upon which the QMS was based. The QMS included and adequately defined the quality policy and objectives. The principles of quality risk management were incorporated into the QMS. The documentation system and hierarchy were described, along with key personnel responsibilities.

Quality unit (QU)

The quality unit had the overall responsibility to maintain and improve the quality systems, procedures, standards, implementation of cGMP, and the quality of the products. The positions of Head Production and Head Quality were separate from each other, with independent responsibilities and reporting.

Management review (MR)

The quality management review followed the respective procedure, which required MR to be conducted on monthly basis for this site for quality issues such as deviation, OOS, change controls and customer complaints. Also, quarterly MRs were conducted on a corporate level, discussing issues related to product quality, marketing, and finance. Senior Management demonstrated a commitment to the QMS by granting adequate resources to implement, support, and manage the QMS. The last quarterly MR meeting was held on 25 August 2023. The meeting minutes and participant list were checked. Key performance indicators were set and monitored.

Product quality review (PQR)

The PQR procedure was in place and described the purpose and application of the procedure. Various elements of quality systems and products were reviewed on an annual basis and completed within three months, according to the procedure. Process capability was calculated. Cpk greater than 1.33 was considered satisfactory, and Cpk from 1 to less than 1.33 was considered good. Values less than one were being evaluated categorically as per the respective procedure. The Quality Assurance Department was responsible for conducting PQRs. The report was reviewed, and statistical analysis was performed on critical process parameters and product quality attributes if 20 or more batches were manufactured during the review period. PQR of several WHO APIs were reviewed.

Quality risk management (QRM)

Quality risk assessments were handled and performed according to a well-established procedure. The risk priority number was determined based on probability (P), occurrence (O), and severity (S). The risk assessment register for 2024 was checked. In general, appropriate instructions were included in the relevant SOPs for the identification, assessment, control, communication, review, and mitigation of risks. A number of risk assessments were checked.

Deviations

A procedure for reporting, investigating, and resolving non-compliances, failures, events, and deviations in a timely manner, was in place. The QA coordinator was responsible for evaluating the completeness and correctness of the incident reports. Investigations had to be completed within the given timelines, and appropriate CAPA had to be applied. Deviations were classified as critical, major, or minor. Investigations were to be closed within 30 days for all deviations according to the procedure. Events were trended on an annual basis. The list of deviations along with a number of selected deviations were spot-checked.

Internal audit (self-inspection)

The self-inspection procedure described the objective, scope, reference document, definitions, and procedure of the internal audit programme. The self-inspection was performed on a half-yearly basis, and a schedule for 2024–2025 was available. The observations were classified as critical, major, or minor. A cross-functional team, along with QA, carried out self-inspections. Self-inspections were performed routinely according to the self-inspection procedure and schedule.

CAPA management

The CAPA procedure was reviewed. The procedure described the steps for identifying and implementing corrective and preventive actions in relation to non-conformances, complaints, deviations, OOS, audit findings, change control, OOT, laboratory incidents, and annual product reviews etc. CAPAs were recorded in a dedicated logbook.

2. Personnel

Personnel qualification

The responsibilities of staff and their specific duties were recorded in written job descriptions. Personnel interviewed during the inspection were aware of the principles of GMP. The job descriptions and responsibilities for key personnel were reviewed.

Personal hygiene

A procedure for personal hygiene was generally followed. Personnel were required to wear protective clothing suitable for the type and stage of manufacturing. Suitable sanitation and change room facilities were provided. Smoking and eating were not permitted in manufacturing areas.

Training

Training was managed according to a well-established SOP. Training was divided into induction, on-the-job, refreshing (when staff has longer than 3 month leave), and external. Training was evaluated through questionnaire and written tests according to established templates, and a passing grade of 80% was set. Assessment records following training were available. The analyst qualification matrix for the year 2024 was checked. The matrix was updated every year.

3. Buildings and facilities

Premises and equipment in the API production area were generally maintained at an acceptable level of cleanliness at the time of inspection. Personnel at the site were seen to be performing their duties in an organized and diligent manner.

Design and construction

The buildings and facilities inspected were designed and constructed to facilitate cleaning, maintenance, and operations as appropriate to the type and stage of manufacture. Manufacturing areas provided good space for the installation of equipment.

Utilities (e.g. steam, gases, compressed air, and heating, ventilation and air conditioning [HVAC] system)

In general, the utilities necessary for production operations were provided and maintained as qualified before use.

The SOP for compressed air along with nitrogen system qualification and trend analysis at NP-1 were checked. The compressed air testing report, the nitrogen gas testing report, the compressed air monitoring data and the Nitrogen gas monitoring data were spot-checked.

Water system

The water generation system was well described in the SMF which reflected the actual installation and operation of the system. Purified water was monitored through a combination of online and offline monitoring. SOPs for sampling, chemical and microbiological examination tests of purified water was in place. Water quality was regularly evaluated through trend analysis on regular basis. The purified water trend at E-18 was verified. The APQR of purified water was also checked.

4. Process equipment

Design and construction

The equipment used in the manufacture of the API and intermediates appeared to be of appropriate design and size for its intended use. In general, cleaning and maintenance appeared satisfactory. Manufacture and material transfer took place in closed systems in many instances.

Equipment installed in the production plants visited were multi-purpose and each piece of equipment had a unique identification number. The measuring equipment were labelled, including calibration status. The inspected equipment appeared to be of suitable design and construction for the allocated process in general.

Equipment maintenance and cleaning

The equipment maintenance and cleaning were appropriately established. An SOP for preventive maintenance was in place. The preventive maintenance planner was verified. Several examples of preventive maintenance were spot-checked.

Calibration

The calibration programme was well established and implemented at the site. The SOP for calibration was followed. The instrument calibration list and the instrument calibration planner were verified and example calibration certificates of temperature sensors and pressure gauges were spot-checked.

Computerized systems

Few computerized systems were used at the site. The Validation Master Plan For Computerized System was in place. The SOP provided for risk assessment along with categorization and subsequent qualification of the computerized systems utilised onsite.

5. Documentation and records

Documentation system and specifications

The company used a paper-based documentation system. The SOP for document control was in place and guided the preparation, issuance, approval, control, review, and withdrawal of procedures and quality documents.

Equipment cleaning and use records

Equipment logbooks for usage and cleaning were maintained. Several logbooks were spot-checked during the inspection including during the site tour.

Master production and control records

Master batch production and control records were in place.

Batch production and control records

Production processes and quality control testing were documented in the form of batch manufacturing and analytical records. The records properly documented the production and control processes with traceability of related activities.

Laboratory control records

In general, documents were designed, prepared, reviewed, and distributed according to a documented procedure. Laboratory control records included complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays. All raw data records and analytical reports were available; analytical reports were approved by lab management. Lab documents were reserved for one year after the product expiry date, according to the procedure for document control, storage, retention, and destruction.

Batch release

The batch release process was guided by the SOP for product release. QA authorized personnel for intermediate/API release were established.

6. Materials management

General controls

The receipt, identification, quarantine, sampling, testing, and approval or rejection of materials were conducted according to approved documented procedure. An ERP system was used in all warehouses.

Receipt and quarantine

Incoming key starting materials and packaging materials were quarantined after receipt until they were released for use. Upon receiving the materials, a check was performed to spot any integrity issues in the consignment and record all consignment details. COA availability with the consignment was checked by warehouse personnel. The sampling procedure and COA checking were performed by QC personnel.

Sampling and testing of incoming production materials

Sampling, testing, and approval or rejection of Key Starting Materials (KSM), packaging materials and finished products (APIs and intermediates) followed well-established procedures. For the new supplier introduced for key material in such cases, to build confidence, 100% sampling was carried out on the first three batches received. For routine sampling, the containers were sampled according to the $\sqrt{n+1}$ formula, and a composite sample was tested as per respective specification for all chemical and microbiological (if needed) tests. The list of suppliers for starting materials was available as a hard copy. Material-dedicated scoops were used during sampling.

In each building (E17 and E18), there was a separate sampling area equipped with a sampling booth linked to a change room for personnel and material passage.

Storage

The warehouse activities were spread over the basement floors of buildings E17 and E18. All KSM and all packaging materials were stored in E17, while E18 stored intermediates (produced by Anuh) and finished products. Both stores consisted of two temperature monitoring areas at 30 °C, three areas with ambient temperatures, and a separate key-controlled samples rejection area. Cleaning records for sampling area E17 were reviewed. Temperatures were monitored in the warehouse by a data logger, and the temperature was recorded manually on a daily basis. Temperature mapping was carried-out.

Supplier evaluation

The procedure for vendor qualification was reviewed. The SOP was applicable to all incoming material suppliers, including packaging material suppliers. According to the procedure, materials were classified by categories: key starting materials, reagents and chemicals, packaging materials, solvents, and miscellaneous items. Critical suppliers (KSM and primary packaging materials) were qualified by a questionnaire, followed by testing of the materials and then performing trials at R&D, followed by a site audit. Suppliers were re-assessed every 3 years for critical suppliers and every 5 years for general suppliers.

7. Production and in-process controls

Production operations were well documented in the form of batch manufacturing and control records (BMCR) and in accordance with the respective master batch records. During the inspection, several actual production operations were observed including centrifugation, drying, blending and packaging.

8. Packaging and identification labelling of APIs and intermediates

The sifting and packing of sulfadoxine at E18 building was witnessed. In general, packaging activities were found acceptable with some observations which were captured in the inspection report and corrected by the manufacturer prior to closing of the inspection and publication of this WHOPIR.

9. Storage and distribution

Dispensing activities were controlled by warehouse personnel, and the staff were following steps from the dispensing procedure. In buildings E17 and E18, there was a separate dispensing area (in the warehouse) equipped with a dispensing booth linked to a change room for personnel and material passage.

10. Laboratory controls

The QC laboratories were separated from the production areas. The laboratories were designed and equipped with facilities for chemical, instrumental and microbiological testing as well as stability chambers.

Testing of intermediates and APIs

Chemical and instrumental laboratory premises were located in the E17 building, on the first floor. The laboratory had adequate space for the orderly placement of equipment and materials and to perform tests. Appropriate specifications were established. Access to lab premises was restricted to authorized personnel.

The microbiological laboratory premises were separated from the chemical laboratory and were located on the second floor of the laboratory building. The microbiological laboratory layout involved separate rooms and areas that provided for media preparation, sterilization, microbial limits, etc. The layout of the laboratory met the requirements for segregation between clean and contaminated laboratory activities. The laboratory had adequate space for the orderly placement of equipment and materials and to perform tests.

Receiving samples

Testing samples were received and tested in the laboratory building. There was a receiving tunnel to receive samples from production for release purposes and another tunnel to receive all other samples for analysis. Receiving and allocation to analysts were conducted and recorded according to the respective SOP. A special sample-locked storage area maintained at 30 °C was available. Logbooks for received KSM, raw materials, IPC samples, and finished products were available and checked.

Qualification of analytical instruments

Most of the laboratory equipment (HPLC and GC) were linked with an electronic software, with some standalone instruments such as UV and IR, as information was saved on the company's server every 8 hours and then saved in the cloud system every 24 hours.

The calibration of the analytical weighting balance was assessed. Daily weight checks were performed in-house for high and low weights, with calibration conducted in-house on a monthly basis for accuracy, reproducibility, and minimal weight. The weights used for daily checks were standardized by an external contractor, and corresponding calibration certificates were verified.

The calibration of HPLC with the latest qualification report was checked. Calibration parameters included: the pump (leakage test and flow rate); the reproducibility and linearity of the injection volume; and the detector.

User privileges procedure for software system management was checked and discussed.

Analytical method validation

The procedure for analytical method validation was reviewed, and it was satisfactory. There was no procedure for validation of the transferred method when product analysis was given to an external laboratory. This was corrected prior to publication of this report.

Stability studies

Stability studies were performed according to a well-established procedure with samples stored in a stability chamber. Temperature and humidity were monitored electronically with the recording of T and RH every 30 minutes and was equipped with an alarm system. Temperature and humidity mapping was carried out every 2 years; the last mapping report for the equipment was reviewed. One batch of products was placed on a stability program yearly. It was noted that stability samples of the finished product were placed in the stability chamber with their primary packaging material. The stability study report for sulfadoxine at a storage temperature of 25 ± 2 °C for 60 months was verified.

Expiry and retest dating

Working reference standards were packed in transparent glass vails and in case of light-sensitive material, amber-colored vials under LAF to be used within one year according to the respective procedure. Working standards were standardized against pharmacopeial standards. The use of reference materials was recorded. Reference material was stored at 2–8 °C. The expiration date for pharmacopeial reference standards was checked online.

OOS Handling

Laboratory OOS were handled according to well-established SOPs. The laboratory OOS register for 2023 was reviewed. Most incidents related to instrument and system suitability failures were identified prior to testing.

Retention samples

Retention samples were stored separately in the laboratory at E17. Enough retention samples were retained to allow two full analyses. Retention samples were stored in the same packaging as for commercial use as per the respective procedure. Samples were subjected to a 100% visual inspection annually, and the register of the same was checked.

Microbiology laboratory

A full set of data was available and was checked for calibration of balances, incubators, fridges, and laminar airflow benches. The laboratory was equipped with two autoclaves, one for decontamination of media and organisms and the other one for sterilization purposes. A horizontal double-door autoclave was used, and the media was loaded from the preparation to the microbial limit test (MLT) area through a tunnel. These autoclaves were validated every 2 years. GPT was performed on each prepared batch of media. Method suitability for MLT was performed.

Release labels

Quarantine labels were printed in the warehouse, while release or approved labels were printed in the laboratory. Approved labels were kept locked in the laboratory and were managed by the label reconciliation register.

11. Validation

Validation policy

Validation policy was guided by the Validation Master Plan (VMP), which was reviewed and found acceptable in general. The VMP provided high-level guidance on different validation and qualification activities including, among others, definitions, general concepts, validation documentation, validation types, process validation (PV), cleaning validation (CV), and analytical method validation (AMV).

Validation documentation

In general, validation documentation was properly implemented in the form of validation protocols and validation reports. The validation reports documented the actual validation activities along with validation results and conclusion. The validation reports were subject to review and approval by quality assurance and the same was indicated within the reports.

Qualification

Qualification activities were performed for equipment and ancillary systems before the commencement of process validation. A number of qualification activities were spot-checked where the same followed the standardized practice of DQ, IQ, OQ, and PQ.

Process Validation

Procedure for process validation was in place for the management of PV activities including life cycle approach of PV. The procedure guided the process validation (PV) activities in terms of process design, process qualification and continued process verification (CPV), along with pre-requisites for PV and PV documentation. A number of process validations were reviewed and spot-checked.

Cleaning Validation

The procedure for cleaning validation was in place. The procedure provided for validation of cleaning processes within batches of the same product and between different products. The CV acceptance criteria were based on the lowest value calculated considering permissible daily exposure (PDE) and 10 ppm of product carryover to the next batch.

12. Change control

Changes were controlled and managed as per a well-established SOP. A number of changes to sulfadoxine and izoniazide were reviewed.

13. Rejection and re-use of materials

Reprocessing was guided by the SOP for reprocessing of material. Reprocessing was only allowed if the relevant process and reprocessing were validated in advance. Reworking on the other hand was not allowed in general.

14. Complaints and recalls

Product complaints followed the principles described in the respective SOP. Complaints were categorized into three levels depending on criticality, with specified timeline requirements for completion. Complaints classified as critical should typically be responded with preliminary investigation within 3 working days, major within 5 days, and minor within 7 days unless otherwise extension was granted by QA. The list of complaints and some selected complaints were spot-checked.

The product recall followed the principles described a well-established procedure. The recalls should be completed within 5 days for the critical recall and 20 days for the major and minor recalls from the date of the recall imitation. No recalls had been initiated for the years 2021, 2022, and 2023. The SOP provided appropriate instructions to recall or remove products from the market. A system for mock recall was in place and the same was verified.

15. Contract manufacturers (including laboratories)

The procedure for the management of external service providers was reviewed. Contracts permitted the contract giver to audit the contract acceptor's facilities for compliance with GMP. Contract acceptor and contract giver responsibilities were clearly defined. External contract laboratory testing was used for a limited number of specialist analytical procedures. Some quality agreements were spot-checked.

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, ***Anuh Pharma Ltd, India*** located at ***E17/3 & 17/4 & E-18 MIDC, Boisar Tarapur Taluka-Palghar, Thane District Maharashtra 401 506, 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 GMP 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://www.who.int/publications/m/item/trs986-annex2

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
   https://www.who.int/publications/m/item/annex-2-trs-957

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.
   Short name: WHO TRS 1010, Annex 9
   https://www.who.int/publications/m/item/trs1010-annex9

4. 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
   https://www.who.int/publications/m/item/annex-3-trs-1033

5. 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://www.who.int/publications/m/item/annex-4-trs-929

6. 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. 957, Annex 1
https://www.who.int/publications/m/item/trs957-annex1

7. 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://www.who.int/publications/m/item/trs957-annex3

8. 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://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
Short name: WHO TRS No. 1019, Annex 2
https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

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://www.who.int/publications/m/item/trs943-annex3

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://www.who.int/publications/m/item/trs961-annex2

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://www.who.int/publications/m/item/trs981-annex2

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://www.who.int/publications/m/item/annex-3-trs-981

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