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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Leping Safely Pharmaceutical Co., Ltd.
Corporate address of the manufacturer	Tashan industry Zone, Leping City, Jingdezhen City, Jiangxi Province 333300, China
Inspected site	
Name & Address of inspected manufacturing site, if different from that given above	Leping Safely Pharmaceutical Co., Ltd. Tashan industry Zone, Leping City, Jingdezhen City, Jiangxi Province 333300, China
Synthetic Unit /Block/ Workshop	Building No 107, Workshop No 7
Inspection details	
Dates of inspection	20 to 23 October 2025
Type of inspection	Initial inspection (New Site)
Introduction	
Brief description of the manufacturing activities	Manufacture, quality control of pharmaceutical intermediates and dyes
General information about the company and site	Leping Safely Pharmaceutical Co., Ltd. was founded in 2006. The site is divided into two parts, north and south. The company mainly produces Tenofovir (PMPA), Benzonitrile alcohol, dispersed yellow, Dispersed red, Dispersed blue, etc. The company declared no toxic or hazardous substances with high pharmacological activity and/or with sensitizing properties were on the premises. Number of personnel employed at the site was 301 at the time of inspection.
History	The site was inspected by US FDA in 2018 and classified NAI. The site has never been inspected by local drug regulatory authority.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document reviewed:** • Quality management • Personnel • Buildings and facilities

	• Process equipment • Documentation and records • Materials management • Production and in-process controls • Storage and distribution • Laboratory controls • Validation • Change control • Rejection and reuse of materials • Complaints and returns **Site area visited:** • Integrated warehouse for solid materials, packaging materials and finished product • Solvents tank farm • Liquids in drums warehouse • Production Workshop No.7 • Quality control laboratory
Restrictions	The scope of the inspection was restricted to the intermediate PMPA (Tenofovir) in the WHO prequalification program.
Out of scope	Products and facilities that are not under the scope of WHO prequalification program.
WHO Intermediate covered by the inspection	Tenofovir (PMPA)

Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
BSE	Bovine spongiform encephalopathy
CC	Change control
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
KF	Karl Fisher
KSM	Key starting material
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Nonconformity
NON-CCOE	Non-chief controller of explosive
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
RH	Relative humidity
RO	Reverse osmosis
SMF	Site master file
SOP	Standard operating procedure
STP	Standard testing procedure
TSE	Transmissible spongiform encephalopathy
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

Part 2	**Summary of the findings and comments**

1. Quality management

A documented system for quality assurance was established, with procedures covering key quality elements in place. The Quality Department was divided into QA and QC and were separate from the Production Department. Operations were specified in written forms and critical GMP requirements were essentially being met. Authorized person for the release of pharmaceutical intermediates was designated.

Product Quality Review
Regular product quality reviews of intermediates were conducted to verify the consistency of the manufacturing process. Such reviews were conducted annually covering the period between January 1st till December 31st each year. According to the SMP "Product annual Quality review", PQR for the current year should be completed within the first quarter of the following year. PMPA annual product review for 2024 was discussed.

Quality risk management
The SMP "Quality risk management procedure" was checked. Various tools were mentioned in the procedure. FTA, Hazard and Operability approach (HAZOP) etc. were mentioned. The FMEA was also mentioned, rating of risks was done including evaluation of Severity, Probability and Detectability. The register for the performed risk was available. The quality risk assessment of cleaning validation of equipment was checked.

Management Review (MR)
The SMP "Management Review" was checked. The procedure defined the process for conducting management reviews and evaluating the performance of its quality systems. It was applicable to the facility involved in manufacturing, testing, procurement, warehouse and related activities of PMPA only and not relevant to the other products produced at the site.

MR was performed annually, and can be initiated when needed e.g. significant change of company structure occurs, severe quality accident and deficiencies etc. The 2024 MR report was reviewed.

Deviations
Deviation from established procedures was documented and explained. Critical deviations were investigated, and the investigations and their conclusions were documented. The SMP "Deviation management procedure" was checked. SOP was applicable to the handling of deviations from procedures or standards related to pharmaceutical production through the entire pharmaceutical production process. Deviations were classified as:
- Critical
- Significant
- Minor

According to the SOP QA was responsible to classify the deviation and investigation. QA was responsible for CAPA follow-up and implementation. Deviation registers for 2023 and 2024 were presented. Examples of deviation investigation reports were checked:

Laboratory incidents
The SMP "Laboratory incidents management" was checked. Laboratory incidents were defined as: any obvious human mistake, instrument malfunction, stability study failure which do not lead to OOS/OOT. Laboratory incidents registers for 2024 and 2025 were presented. Examples of laboratory incidents investigation forms were verified.

Handling of CAPA
The SMP "CAPA management" was applicable to, but not limited:
- Complaints
- OOS
- Recalls/returns
- Deviations
- Self-inspection
- Routine non-conformities

- Rejection
- Management review
- Regulatory inspection findings
- Laboratory incidents
- APQR

According to the SOP CAPAs were classified as:
- Critical
- Major
- Minor

CAPA registers for 2024 and 2025 were presented. Closure time of CAPAs was indicated as well as classification and root cause.

Root cause investigation (RCI)
The SOP was applicable to all investigations carried out at the facility.

Self-inspection
The SMP "Internal Audit" to ensure compliance with current Good Manufacturing Practices (cGMP) was checked. This procedure covered various departments, including manufacturing, quality control, quality assurance, training, and warehouse management, and engineering. The audit team should consist of at least 3 trained, experienced and knowledgeable auditors. Lead auditor was head of QA. Conflicts of interests was avoided. Deficiencies were classified as:
- Critical
- Major
- Others

System based internal audit was carried out annually, covering all GMP related activities. Deficiencies identified were escalated to the management review meeting. Last self-inspection was carried out using department systems-based check lists. CAPAs were proposed by inspected department/system, CAPA implementation was checked by QA and approved by the Head QA.

Data management
The following procedures were checked:
- The SMP "Data integrity". The document defined ALCOA principle and data integrity police.
- The SMP "Electronic data". The document defined user levels of OpenLab software. The privileges were checked and discussed.

Batch release
The SMP "Finished product release audit" was checked. The product release of PMPA intermediate was responsibility of the Quality Manager. The responsibilities were defined as follows:
- Production: review and submission of completed BPR
- QC: review of batch analytical records and submission of raw data to QA
- QA: review of BPR and batch analytical records
- QA manager: release of the finished product batch. Checklist was used for batch release.

The batch release register was maintained. The release and review forms for a batch was checked.

2. Personnel

The company maintained an organogram. Production and Quality functions operated independently. The Head of Production and Head of Quality Department reported directly to the General Manager.

In general, there was an adequate number of personnel qualified by appropriate education, training, and/or experience to perform and supervise the manufacture of intermediates. The responsibilities of personnel engaged in the manufacture of intermediates were specified in their respective job descriptions.

All key positions in production, quality assurance, and quality control had been filled. The job descriptions were described and verified. Total number of personnel according to the company presentation was 301.

Personnel hygiene

The following SOPs were checked:

- The SMP “Personal health management procedure”.
- The SMP “Personnel hygiene”.

Training

The manufacturer had established a documented training program following a written procedure. Annual training plan for 2025 was presented.

Analyst’s qualification procedure was explained in a written procedure.

3. Buildings and facilities

In general buildings used in the manufacture and testing of intermediates and APIs were properly maintained and kept in a clean condition. Buildings and facilities had adequate space for the orderly placement of equipment and materials. The buildings and facilities were dedicated to production and testing of PMPA.

4. Process equipment

Design and construction

Equipment used to manufacture the intermediate was located for its intended use, cleaning and maintained at acceptable level. All equipment was dedicated to PMPA intermediate manufacturing.

Equipment Qualification

The equipment qualification was performed following SMP “Equipment qualification”. Equipment requalification was required to be performed periodically. If there was a deviation, the time period of requalification should be shortened.

Equipment maintenance

The SMP “Equipment maintenance” was checked. The 2025 equipment preventive maintenance plan and implementation status was presented. The preventive maintenance record of a centrifuge and a dryer were checked.

Equipment cleaning

The SOP “Synthetic equipment cleaning procedure” was made available. The SOP explained batch to batch and campaign cleaning. The cleaning was recorded in the BMRs. The cleaning procedure for the blender after campaign production was checked.

Calibration of Equipment
All equipment contained calibration labels, showing calibration date and due date as well as "status tags" and preventive maintenance labels. Control, weighing, measuring, monitoring, and test equipment critical for assuring the quality of intermediates or APIs were calibrated according to written procedures and were within the established schedule.

5. Documentation and records

Documents related to the manufacture of intermediates and PMPA were prepared, reviewed, approved, and distributed according to respective SOPs. Documents were maintained in paper form.

"SMP of documentation" was checked. QMS system documents, operations procedure and SOP were reviewed periodically. Manufacturing related documents were maintained for the specified period of time. Documents such as product specification were maintained long term.

Batch numbering system and Batch production records
"SMP of batch number, production date, retest date (expiry date)" was checked. The rule for batch numbering was described in the procedure. The company also had a procedure "SMP of material code" in place, which defined the code of material and finished products.

Master production instructions
Master production instructions were prepared, dated and approved, and contained detailed guidance on production activities.

Batch production records
The batch production records were managed in accordance with the following procedures. The batch production records issuance was checked and discussed.

- "SMP of drafting and management for Batch production records"
- "SMP of template of review, distribution and return of blank BPR".

The BMRs of PMPA were checked. In general batch production records included adequate information relating to the production and control of the batch.

Materials management
A system was established for the evaluation and approval of suppliers of critical materials. Materials were procured in accordance with agreed specifications from approved suppliers. Materials were handled and stored in a manner that prevented degradation, contamination, and cross-contamination. Materials stored in fiber drums, bags, or drums were kept off the floor and suitably spaced to permit cleaning and inspection. Receiving and dispatch bay for solid materials protected materials from the weather. Temperature and RH in solid and final PMPA warehouse was monitored and recorded twice per day.

An approved suppliers list was available in the warehouses. Materials were received according to the check list. Movable quarantine area was used to separate materials under quarantine from released materials. Separate locked place was assigned for storage of rejected solid materials.

Sampling plan for solid materials and liquids in drum was defined. The containers from which samples were taken were labelled. Release labels were affixed to each material item.

Vendor management
The SMP "Supplier management" was checked. Procedure specified qualification and requalification of vendors supplying raw materials, process aid materials and packaging materials. QA was responsible for approving specifications, establishing suppliers audit plan, evaluation of samples, organizing of on-site audit, approve and maintain approved suppliers list, approving quality agreements with customers and approve suppliers. Materials were classified as:

- Critical
- General

For critical materials on-site audits were performed every 3 years. General materials suppliers were approved based of questionnaires. Suppliers audit schedules for 2023, 2024 and 2025 were reviewed. Checks proved that audit schedules were followed, and audits/questionnaires were performed in a timely manner. The audit report of a critical starting material manufacturer and the quality agreement was checked.

Production and in-process controls
The production workshop 7 was dedicated to PMPA manufacturing. PMPA was produced by a single process and supplied to several API manufacturers as an intermediate for further processing. PMPA production was in operation during the inspection. The relevant production areas were visited. Raw materials for the manufacturing of intermediates PMPA were weighed or measured according to the BMRs. Weighing and measuring devices were of suitable accuracy for the intended use.

Blending of batches
The PMPA commercial batch was blended with two or more dried crystallization batches. The "SOP of mixed batch, packing process" was checked and discussed.

6. Packaging and identification labelling
Inspectors visited blending/packaging room. Packaging operations were not carried out during the inspection, therefore not inspected. Labels applied to the PMPA containers were printed by the sales department and checked by QA. Samples of labels used were kept by QA.

7. Storage and distribution
Warehousing procedures
Facilities were available for the storage of materials under appropriate conditions. Records of these conditions were maintained. Materials management system/inventory system was manual by using inventory cards.

Distribution procedures
Commercial batches of PMPA were released for distribution to third parties after approval by the QA manager.

8. Laboratory controls
Quality control laboratory was provided with adequate laboratory facilities. Written procedures were established and implemented for sampling, testing, approval or rejection of materials, as well as for the storage and retention of laboratory data.

Reagents and standard solutions were prepared and labelled in accordance with requirements. Volumetric glassware was identified with unique numbers and calibrated annually by the third party. Laboratory instruments were calibrated by the third party and qualified by laboratory staff annually.

Sample receiving and distribution
Samples from the workshop were received via a separate entrance. Dried PMPA samples were taken by workshop personnel, blended batch samples were taken by QC personnel. Analytical tests were assigned to analysts based on documented competency list.

Testing of materials
The following documents were checked.

- Standard test procedure “Quality specification of dried batch-crystallisation batch”
- “Quality specification of blended commercial batch” were checked and discussed.
- SMP “Issuance of original analytical record form and CoA procedure”.

Tests reports (TR) were issued by QA. The CoA of a Tenofovir commercial batch was checked. CoA was signed by analyst and reviewed by QA.

OOS management
OOS was managed according to “SMP of OOS/OOT”. The procedure applied for raw material, intermediate, finished product and stability study. An OOS investigation should be complete within 30 working days upon the procedure. The OOS registers were in place. An example of OOS handling was checked and discussed.

Retention samples
Retention samples were managed according to “SMP of reserved sample”. Appropriately identified retention samples of each PMPA commercial batch were retained for one year after retest date assigned by the manufacturer. Samples were stored in the packaging equivalent to the marketed packaging of PMPA in a temperature monitored room. Sufficient quantity was retained to allow for two full specification analyses. The retention sample register was available and checked.

Stability study
The “SMP of stability study” was checked. Initial (long term and accelerated stability study) and ongoing stability studies were defined. The procedure specified stability study conditions, timeline for inward and withdrawn for testing etc.
The stability study report of PMPA was checked. PMPA stability study were performed under condition of T 25 °C ± 2°C, RH 60% ± 5%.

9. Validation
Validation was performed following “SMP of validation”. The procedure defined the policy for process validation and cleaning validation. Process validation should be performed either prospective or concurrent with three consecutive batches.

Process validation
The “SMP of Revalidation” was checked. Re-validation or re-qualification was required whenever changes were introduced to the facility, manufacturing process, specifications, processing equipment etc. that may impact the validated status. Such changes must be assessed, and if deemed significant, must trigger re-qualification. Revalidation time interval was defined in the procedure if there were no changes.

The PV documents for PMPA performed in 2025 were checked. The PV was trigged by new equipment introduced to the production.

Cleaning validation:
The equipment was dedicated to the PMPA production. The SOP “Equipment cleaning procedure” was available. The risk assessment of cleaning validation of equipment related to PMPA was spot checked. Due to time constraints, the cleaning validation was not inspected in detail.

Computerized system validation
The computerized system was implemented in the chemical laboratory. Computerized systems were not used for production and material control. Due to time constraints, the computerized system validation was not inspected in detail.

10.Change control (CC)
“SMP of change control” was checked. Changes were classified into permanent or temporary change. The SOP covered the identification, documentation, review, and approval of changes. Changes were defined as:
- Other
- Critical

Change register was maintained, and examples of change were checked.

11.Rejection and re-use of materials
Rejection
The SMP “Handling of non-conforming products” was checked. SOP was applicable to non-conforming raw materials, packaging materials, intermediates and finished products as well as returned and recalled products. Materials which did not meet established specifications were identified and quarantined. The final disposition of rejected materials was required to be documented. According to the SOP, materials manufactured at Leping could be reprocessed.

Rejected materials were labelled as such, labels were affixed to each container and stored in the rejected materials warehouse/area. In general, rejected materials were returned to the suppliers. List of non-conforming products 2025 was presented.

Reprocessing and reworking
The SMP “Reprocessing and recovery” was checked. According to the SOP reworking was not allowed. The need of reprocessing was determined by production and approved by QA,

Recovery of materials and solvents
The company declared that recovered solvents and recovered second crops were not used in the manufacturing process.

Returns
The SMP “Handling of returned products” was checked. According to the SOP QA shall evaluate returned product:
- If there was any damage
- Labelling
- Dirty packages
- Had sampling preformed and were packaging intact
- Returned quantity
- Visual check of appearance of material
- Transportation meets required storage conditions.

Until the date of inspection no products were returned.

12.Complaints and recalls
All quality-related complaints, whether received orally or in writing, were recorded and investigated according to SMP "Complaints management procedure".

According to the SOP sales department was responsible for collecting compliant information and transmitting received information within one day to the QA. QA assigned the complaint number and issued a complaint investigation form. QA manager/QP was responsible for complaint investigation. QA was responsible for CAPAs implementation.

According to the SOP complaints were classified as:
- Critical quality complaint. Definition: serious quality defected which could cause return, recall, detentions, local warning or possible notification by government health agencies
- General quality complaints.

The timeline for investigation was specified in the procedure. According to the impact assessment procedure, investigations must be extended to other batches. If required appropriate actions should be initiated for product recall. Complains were reviewed regularly. An example of compliant was checked and discussed.

Recalls
The SMP "Product recall" was discussed. The SOP was established to define the circumstances under which a recall of a PMPA would be considered. The recall procedure specified responsibilities for evaluating information, the process for initiating a recall, individuals and authorities to be informed, and the handling of recalled materials. In serious or potentially life-threatening situations, local, national, and/or international authorities as well as customers were informed. A mock recall was carried out every 3 years. The last mock recall was carried out in September 2025. Till the date of inspection, no recalls were carried out. There were two types of recalls specified:
- Voluntary
- Mandatory

Recalls were classified as:
- Class I, should be initiated within 24 hours from initiation of procedure
- Class II, should be initiated within 48 hours from initiation of procedure
- Class III, should be initiated within 72 hours from initiation of procedure

13.Contract manufacturers (including laboratories)
Manufacturing or testing activities were not contracted out.

Part 3	Initial 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, ***Leping Safely Pharmaceuticals Co., Ltd.,*** located at ***Tashan industry Zone, Leping City, Jingdezhen City, Jiangxi Province 333300, China*** was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for active pharmaceutical ingredients.

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.

The 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 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 GMP for APIs or WHO TRS No. 957, Annex 2***
   http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

2. 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***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. 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**
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

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
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

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
   http://www.who.int/medicines/publications/44threport/en/

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 2.
   Short name: WHO TRS No. 957, Annex 2
   http://www.who.int/medicines/publications/44threport/en/

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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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**
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
    http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

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
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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***
    http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
Short name: WHO GDRMP guidance or WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

22. WHO general guidance on variations to multisource pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report. Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO Multisource guidance or WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. 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

24. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1015), Annex 3.
Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications-detail/978-92-4-000182-4

25. 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

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
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