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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	**Lupin Limited, Nagpur**
Corporate address of the manufacturer	Kalpataru Inspire 3rd Floor, Off Western Express Highway Santacruz (East) Mumbai 400055, India
Name & address of inspected manufacturing site if different from that given above	Unit 1, Plot No.6A 1, 6A2 Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra-441108, India
Unit/block/workshop number	Block-2 (Block-1 having chemical and microbiology laboratory)
Dates of inspection	8-11 September 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	The manufacturing facility is located at Unit 1, Plot No. 6A1, 6A2 Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra-441108, India. The site is approximately 15 km from Nagpur Railway Station and 10 km from Nagpur Airport. The facility at Nagpur (Unit 1) is engaged in the manufacturing of Solid Oral Dosage Forms for the USA, Europe, Australia, Canada, Uganda (NOA), WHO (Geneva), Germany, South Africa, Ukraine, New Zealand, France, Oman, and ROW markets.
General information about the company and site	Lupin Limited is one of the leading Indian Pharmaceutical Public Limited Companies. Lupin Limited has its headquarters in Mumbai, India. It is a multidivisional and multi-locational organization. The company was founded in 1968 and is currently engaged in the manufacturing of Formulations, APIs, and biotechnology-based products.
History	The manufacturing site has been regularly inspected by the WHO Inspection Services, Geneva. The last on-site inspection was conducted in September 2018, whereas desk assessments were performed in 2022 and 2024.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management system - Personnel, hygiene, sanitization, and training - Validation and qualification - Production and packaging operations

	- Quality control and microbiology laboratories - Material management, including supplier qualification and warehouses - Facilities and instrumentation (including in-process and QC) - Utilities, including the water system and air handling units
Restrictions	None
Out of scope	Products out of the WHO's interest.
WHO products covered by the inspection	1. Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg (HA703) 2. Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg (HA715) 3. Atazanavir (sulfate)/Ritonavir Tablet, Film-coated 300mg/100mg (HA720) 4. Dolutegravir (sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet/DLTDF, Film-coated 50mg/300mg/300mg (HA737) 5. Abacavir (sulfate)/Dolutegravir (sodium)/Lamivudine Tablet, Dispersible 60mg/5mg/30mg (HA790) 6. Emtricitabine/Tenofovir alafenamide Tablet, Film-coated 200mg/25mg (HA805, under assessment) 7. Dolutegravir (sodium)/Lamivudine/Tenofovir alafenamide Tablet/DLTAF, Film-coated 50mg/300mg/25mg (HA806, under assessment) 8. Dolutegravir (sodium)/Emtricitabine/Tenofovir alafenamide Tablet/DETAF, Film-coated 50mg/200mg/25mg (HA807, under assessment)
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
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

The QM of the Company issued by the Corporate, described the quality management system/QMS, management's participation, and the roles of relevant personnel. The document encompassed QMS, management review, training, product development, facility and equipment, computerized systems, documentation and records, material management, manufacturing, distribution, change management, quality system, quality control, validation, technology transfer, reprocess and rework, returned products, audits and inspections, and quality risk management. The general responsibilities of the site QA were summarized in the SOP. The quality unit was independent of production and fulfilled both

quality assurance (QA) and quality control (QC) responsibilities. It was responsible for the following functions:

- Releasing or rejecting raw materials, intermediates, packaging and labelling materials, APIs.
- Reviewing completed batch production and laboratory control records of critical process steps before release of the API for distribution.
- Making sure that critical deviations were investigated and resolved. Internal audits (also known as self-inspections) were performed. Approving intermediate and API contract manufacturers.
- Change control, deviation investigation, complaint investigation, equipment maintenance and calibration program, quality control testing, stability program, PQR preparation and approval, reviewing all production batch records, approval of the GMP core documents, amongst others.

Product quality review

The annual product quality review (APQR) of drug products was discussed. The APQR was conducted every 12 months following the approval/anniversary of the respective product. One common APQR was prepared when the product has the same manufacturing process with a different presentation. A separate APQR was prepared when the manufacturing process for the same product differed. The process capability criteria were established in the SOP. If the CpK value was reported below 1.0, a process improvement plan (PIP) would be proposed. Minitab software was used for calculating the CpK. The procedure also referenced the CpK improvement action plan.

Change controls

The changes were handled in Caliber QAMS in accordance with the SOP. The changes were classified as major or minor. For the major changes, a quality risk assessment was mandatory for all participants, but optional for minors. The process steps consisted of safety assessment, regulatory assessment, QA final assessment, and execution of the action plan.

Quality risk management/QRM

The SOP for QRM was reviewed. The procedure described the use of a prospective (proactive) and a retrospective (reactive) approach for assessing the risks. The procedure described the use of various tools, but FMEA was used for both proactive and reactive risk assessment. The procedure was prepared in accordance with the current references, including ICH Q9 (R1).

Management review/MR

The SOP for the MR of quality metrics was discussed. The procedure described three key meetings: the site quality council meeting, the quality council meeting, and the global quality council steering committee meeting, and the frequencies were described accordingly. The QA was responsible for ensuring meetings were conducted as planned and followed the agenda outlined in the procedure.

Deviation management

The deviations were defined and handled in the QAMS in accordance with SOP. The deviations were categorized as critical, major, and minor.

Corrective and preventive actions/CAPA management

CAPA actions were triggered by quality complaints, product failures, OOS/OOT/OOC results, recalls, returns, deviations, internal/external audits, authority inspections, rejections, management reviews, trends, analytical deviations, APQRs, QAS improvements, risk assessments, and GAP analyses. The

SOP contained the process steps and the process flowchart as managed and recorded in the QAMS system.

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

Manufacturing processes were clearly defined in electronic BMRs. During the inspection, the manufacturer demonstrated a high level of competence in all the discussed areas. Qualifications and validations were performed in a timely manner in accordance with annual schedules. The personnel who met (subject matter experts) were experienced, qualified, and trained. The premises were sufficient, with state-of-the-art, well-maintained equipment. Material management and warehousing were exemplary. The document management system was helping the company transition to a paperless environment. The quality control and the IPQC had adequate personnel, laboratories, and equipment. A system was in place to record, handle, and investigate deviations, changes, and quality complaints in a timely manner.

Block 2 was a shared manufacturing facility that manufactures products for different therapeutic areas. No manufacturing activities were carried out in Block 1, and they were relocated to Block 2, except for the laboratory.

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

3. Sanitation and hygiene

Written facility cleaning, sanitization, line clearance, and gowning procedures were in place to ensure high levels of sanitation and hygiene (see relevant sections).

4. Qualification and validation

The validation master plan (Block-2, Unit-1) was developed to implement the company's validation philosophy. The document was reviewed every two years and covered areas such as processes, cleaning, analytical methods, computer system validation, qualification/requalification of equipment and instruments, analyst qualification, periodic qualification & validation, vendor qualification, computerized system validation, and change control, among others. The VMP schedule for 2025 was available, listing the equipment/systems due for periodic assessment and requalification. The risk assessment was performed three years after the initial qualification to determine the need for requalification, using Categories 1 (critical) to 3 (non-critical). If no changes were made and the risk was low, requalification would be performed every 5 years. For high-risk equipment/instruments, the period was 3 years.

The protocols and reports pertaining to process validation, cleaning validation, computerised system validation, and analytical method validation were reviewed and found to be adequate.

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

5. Complaints

The complaints were received by the Market Complaint Group and recorded in the QAMS system in accordance with SOP. The corporate QA reviews the major & critical complaint investigation report prepared by the site before sending it out to the complainant.

6. Product recalls

Product recalls were managed in accordance with SOP. By classification, the complaint could be:

- Critical, Major, or Minor.
- Voluntarily or statutory
- Customer level, retail level, wholesaler level,

7. Contract production, analysis, and other activities

No manufacturing activity was contracted out.

The qualification of contract laboratories and raw-material vendors was primarily managed at the corporate level, with limited involvement from the Site.

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

Regular internal audits were performed in accordance with an approved schedule and the SOP. The schedule for the year 2025 was available, assuring the annual inspection of every department:

- Process development Laboratory, Warehouse, Technical training, Validation, Engineering,
- Quality Control, HR/Administration, Production, Engineering, IT, EHS

Audit findings and corrective actions were documented and presented to the firm's management. Agreed, corrective actions were completed in a timely and effective manner.

9. Personnel

General

The department-wise employees of the manufacturer (permanent and temporary) are as follows:

- Manufacturing (incl. production and packaging, 326),
- Quality control (incl. chemical and microbiological, 144),
- Quality assurance (80), Engineering (42), Warehouse (40),
- Process development (26), IT (6), Other (31).

Manufacturing operations run in 4 shifts as follows:

- General shift: 9-17.45h and First shift: 7-15h
- Second shift: 15-23h and Third shift: 23-7h

Job descriptions

The responsibilities of all personnel engaged in the manufacture of drug products were specified in job descriptions. The positions and reporting lines outlined in the job descriptions aligned with the organizational charts. The job descriptions of the following staff were discussed:

- Jr Officer Production, Coating
- Manager Production, Coating
- GM Quality Assurance
- Manager QA, Documentation

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

10. Training

Staff training was regularly conducted by qualified individuals and covered the operations employees performed, as well as GMP sections relevant to their functions. Records of training were maintained. The training system was periodically assessed in accordance with SOP. The training system was managed by the SABA software. The software's User Manual contained information on its functions and operations. The training records of the Jr Officer Production, Coating were discussed.

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

11. Personal hygiene

The personnel hygiene rules were described in the SOP. The medical examination of the entire staff was required upon joining the company, and then annually by a contracted service provider.

12. Premises

Production in Block 1 was stopped, and most of the process equipment had been relocated to Block 2, where the process steps were conducted in closed systems. The cubicles were multifunctional. All the production cubicles with the potential of powder generation were equipped with sink-principle pressure-cascade airlocks. The airlocks had sliding doors on both sides. The manufacturing processes were recorded in an electronic batch record (PAS-X).

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

13. Equipment

The company had the appropriate number and capacity of process equipment in place, with product contact parts made of stainless steel. The equipment parts were detachable and removable for cleaning in the washing area located on the 1st floor. The operation was assisted by qualified and validated PLC systems. The newly purchased or modified equipment was qualified before usage, then regularly requalified and maintained. The measuring devices were calibrated in accordance with the annual calibration schedule. The instrument logbooks were electronic.

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

14. Materials

Written procedures were in place to describe the receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of materials. Upon receipt, incoming materials were visually examined, dusted, and weighed prior to acceptance. In the event of a discrepancy, the QA was notified. The GRN (Goods Receipt Note) was generated in the SAP, containing the relevant information of the shipment and the materials. The warehouse officers, executives, and managers had the privilege to prepare the GRN, which was always cross-checked by another person. The QC received the GRN electronically from the system as the sampling request. The status control of the materials in the warehouse was logical without physical movement, but status labeling was performed as follows:

- Under test/Quality inspection
- Unrestricted use/Approved
- Blocked (with physical segregation)
- Restricted (temporary action)

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

15. Documentation

Written procedures were in place for handling various document types, including SOPs. The preparation of a new document or a revised version of an existing document was supported by change control. The SOPs were managed in the Caliber Electronic Document Management System (EDMS) in accordance with the SOP. SOPs specified that all quality-related activities should be recorded at the time they were performed. The majority of the quality assurance documents were prepared and handled electronically.

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

16. Good practices in production

The manufacturing facility was well-equipped with equipment and instruments. The area housed granulation suites comprising FBD, RMG, sifter, compression cubicles, coating sections, and bottle packing lines. The recent status of the products in the scope of the inspection was as follows:

Product	Validation	BMR	Commercial production
HA703	In Block 1 (obsolete)	Paper-based (obsolete)	None
HA715	In Block 1 (obsolete)	Paper-based (obsolete)	None
HA720	Validated in Block 2	Electronic	Commercialized
HA737	Validated in Block 2	Electronic	Commercialized
HA790	Validated in Block 2	Electronic	For the non-WHO market
HA805	In Block 1 (for registration only, obsolete)	Paper-based (obsolete)	None

HA806	In Block 1 (for registration only, obsolete)	Paper-based (obsolete)	None
HA817	Validated in Block 2	Electronic	For the non-WHO market

The inspectors visited the production and packaging areas where WHO-prequalified and under-assessment products were produced. Generally, the production/packaging areas were well-maintained.

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 inspector visited the quality control laboratory. The laboratory has 143 staff, including 6 microbiologists. The laboratory had 59 HPLCs of different makes, 6 GC headspace units, and was operated using Chromeleon 7.2.10. The laboratory was in the process of upgrading to 7.3.2, MU.

Stability study

The procedure for managing stability studies was discussed. The procedure provided a stability study process flow diagram from the receipt of samples from IPQC through analysis, reporting, and final review by QA. The storage conditions were described in the procedure for exhibit batches. The procedure referred to the annual stability program.

Out of specification (OOS)

The SOP for handling OOS test results was reviewed. The procedure was supported by a process flow diagram, and hypothesis testing was conducted to identify any obvious errors.

Out of trend/OOT

The SOP for trend analysis of quality parameters and out-of-trend investigation was discussed. The procedure described different criteria for OOT for exhibit stability batches, commercial stability, and commercial release. Minitab software was used, and criteria such as UCL/LCL, 6 points increasing/decreasing, and controlled limit were described in the procedure. In general, the procedure was considered adequate.

The microbiology laboratory was not visited due to time constraints.

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, ***Lupin Limited, Nagpur,*** located at ***Unit 1, Plot No.6A 1, 6A2 Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra-441108, 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

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***
Essential Medicines and Health Products Information Portal (digicollections.net)

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
https://www.who.int/publications/m/item/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6

21. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4***
9789240020900-eng.pdf (who.int)

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 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. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning 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**
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25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
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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**
9789240001824-eng.pdf (who.int)

27. 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. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***
https://www.who.int/publications-detail/978-92-4-000182-4

28. 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