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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	**Ipca Laboratories Limited**
Corporate address of the manufacturer	Ipca Laboratories Limited 48, Kandivli Industrial Estate, Kandivli (W), Mumbai, Maharashtra, India
Name & address of inspected manufacturing site if different from that given above	Ipca Laboratories Limited (SEZ Indore, Pithampur) 1 Pharma Zone, SEZ Indore Pithampur, Madhya Pradesh 454775 India
Unit/block/workshop number	General OSD Block
Dates of inspection	23-27 June 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Ipca Laboratories Limited SEZ-Pithampur is involved in the manufacturing of non-sterile pharmaceutical solid oral dosage forms, including tablets and capsules, encompassing the entire process from manufacturing through packaging, analysis, and distribution of finished products.
General information about the company and site	Ipca Laboratories Limited is one of the leading Pharmaceutical Companies in India, with manufacturing operations in pharmaceutical dosage forms, Active Pharmaceutical Ingredients (APIs), and Drug Intermediates.
History	This is the routine GMP inspection by the WHO PQ. The last on-site PQ inspection was performed in 2011. The desk assessment was conducted in 2022.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: 1. Pharmaceutical quality system 2. Personnel and training 3. Complaints and recalls 4. Production and packaging practices 5. Laboratory practices 6. Utilities (purified water and air handling units)
Restrictions	None
Out of scope	Products not submitted to the WHO Prequalification were excluded from the scope of this inspection.

WHO products covered by the inspection	1. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg (MA136) 2. Artemether/Lumefantrine Tablet 20mg/120mg (MA062)
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 (where applicable)**

1. Pharmaceutical quality system

A documented quality management system covering key GMP and quality elements was established and implemented at the site. Key aspects of the quality management system were documented in the quality manual. The QA and QC functions were independent of the production department. Operations were documented, and critical GMP requirements were essentially met. Corporate and site-specific procedures reviewed and discussed during the inspection were generally acceptable. The manufacturer used various electronic systems to manage quality, materials, laboratories, and other functions.

Management Review Meetings (MRMs).

MRMs were conducted to evaluate the effectiveness of the pharmaceutical quality system were governed by the corporate procedure. The MRMs were conducted quarterly at all IPCA sites. A corporate senior management team was established and required to attend each meeting in addition to each site's QA, QC, Production Head, and Site Head. The meeting records for Jan-March 2025, conducted on 15/05/2025, including the list of participants, action points, and presentations, were reviewed. A separate corporate SOP described the quality metrics and targets to be reviewed during MRMs.

Product quality review/PQR

The PQR procedure was discussed, which applied to sites manufacturing formulation products. The PQR was performed annually, covering all products manufactured on-site. The procedure allowed PQR to be performed either on a calendar year or on a rolling basis. The site followed a rolling 12-month period. More than 30 batches were required for performing statistical analysis, including CpK, whereas trending and statistical analysis would be performed if fewer than 30 batches were manufactured (no CpK). The Cpk criteria were defined in the procedure, which also described actions to be taken if the Cpk criteria were not met. The SOP included various QMS elements as required in the WHO GMP Guide.

Deviations.

Deviations were managed in the TrackWise software and governed by the corporate procedure. Deviations were required to be reported as soon as possible, within 1 working day of the occurrence. An impact assessment, including immediate actions, was performed by QA and the department Head, and deviations were classified as major or minor. This classification was based on the impact of the deviation on product quality. Investigations were required to be conducted by cross-functional departments in accordance with the root cause procedure, risk assessments in accordance with the quality risk management SOP, and corresponding CAPA in accordance with the SOP. A 30-day timeline was set for the investigation and closure of deviations. Periodic trending of deviations was to be performed every 6 months.

Change Management.

Changes to facilities, procedures, equipment, and processes were managed in accordance with a corporate procedure. Changes were classified as temporary (time-limited) or permanent. A change control review board, a cross-functional team, was constituted to perform a cross-functional impact assessment. Changes could further be clarified as major or minor. Changes were initiated in the TrackWise software, reviewed, and approved by the Head of Department. QA was responsible for classifying changes based on their impact assessments and site approvals. Changes having an impact at the corporate level were reviewed by the corporate technical committee prior to approval. Timelines for the management of changes were described in the SOP (150 to 180 days) for major changes, (30 to 90 days) for minor changes, and 90 days for temporary changes. A maximum of 3 extensions was allowed, with the third change requiring CQA approval. The head of QA or a designee was responsible for conducting a post-implementation impact assessment of applicable changes.

Quality risk management (QRM)

The QRM procedure was prepared in accordance with ICH Q9 (R1) and other relevant references. The procedure described various tools used for the risk assessment. The CSOP incorporated the changes proposed in the revised ICH guideline. In 2025, the site initiated and conducted several risk assessments related to introducing new products, the number of batches required for process validation, increasing batch size, and more.

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

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources, including adequate premises, equipment, and utilities, were provided to support the current operational level of finished pharmaceutical products manufacturing activities. The manufacturing processes followed procedures as defined and documented in the BMRs. The personnel were appropriately qualified. The manufacturing facility where WHO-prequalified non-sterile products were produced was a shared facility.

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

3. Sanitation and hygiene

Sanitization and hygiene practices were followed during the manufacture of finished pharmaceutical products. The personnel were required to follow the gowning procedure before entering the manufacturing areas. The 70% IPA was used to sanitize hands before entering the manufacturing areas. The manufacturing areas were temperature and humidity-controlled. The pressure differential between different room grades was monitored and recorded. The primary gowning was changed twice per week.

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

4. Qualification and validation

The Validation Master Plan (VMP) and qualification guided the manufacturing sites in preparing the VMP. The VMP was reviewed, and it was noted that it is a site-specific VMP, reviewed every 2 years or when changes are required. The VMP included areas such as equipment qualification and process validation (e.g., cleaning, process, analytical, and computer systems). The VMP schedule was prepared on an annual basis, which included periodic verification of the compressed air system, temperature mapping, equipment related to manufacturing and packaging areas, cleaning validation, HVAC, process validation, hold time study, analytical method validation, building maintenance schedule, environmental monitoring schedule, water monitoring, computerized system validation, calibration schedule, preventive maintenance schedule, transport validation, PLC validation etc. The VMP schedule was prepared and approved by the QA.

The protocol and reports pertaining to cleaning validation, process validation, and computerised system validation were reviewed.

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

5. Complaints

Complaints were managed in accordance with the corporate SOP for handling product complaints. The scope of the procedure applied to manufacturing, packaging, adverse drug reactions, purity, safety, efficacy, and drug quality-related complaints received at the site. Complaints were received at the corporate level via email, letters, and verbal notifications. A site coordinator was designated for each site to manage complaints. The site coordinator was responsible for initiating investigations into complaints with other departmental Heads. The initial classification of the complaint was performed by corporate QA, and after completion of the investigation, root cause determination, and impact assessment, the final classification was made by the site QA. Complaints were classified as critical, major, or minor based on their impact on product quality. Timelines for investigating and resolving complaints were tailored to each complaint's criticality. Complaints of a critical nature were to be communicated by the Head QA to the concerned Regulatory Authorities or customers. Complaints were closed after the investigation report was shared with the customer, including proposed CAPAs. Effectiveness checks were required for high-, medium-, and repetitive-complaints. Trends in complaints were monitored annually and quarterly. No complaints regarding the WHO prequalified products had been registered.

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

6. Product recalls

A product recall procedure outlined the steps for withdrawing defective products or batches from the market. According to the procedure, the recall decision was made by the company's managing director. Recalls were classified as voluntary or statutory, and, depending on the risk to the patient's health, they were categorized as Class I, II, III, or IV, corresponding to caution-in-use notices. The depth of the recall was defined in the SOP class (consumer/patient level, retail level, wholesale level, and hospital level), and this was linked to the recall class. Class I recalls were required to be initiated within 24 hours and completed within 72 hours; Class II recalls were initiated within 48 hours and closed within 10 days; while Class III recalls were initiated within 5 days and completed within 30 days. The company had not reported any product recalls within the last five years.

7. Contract production, analysis, and other activities

The WHO prequalified products were manufactured by the Ipca Pithampur site, and there was no contract manufacturing carried out for these products. Some of the tests were outsourced by the manufacturer, and quality agreements were in place.

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

Self-inspections were conducted in accordance with the corporate procedure. An annual self-inspection schedule was in place and covered all GMP-applicable areas. Self-inspections were conducted at least twice each year and also on a risk-based basis, such as in response to major complaints and recalls. The self-inspection team comprised QA and one other member from another department, excluding the auditee department. Auditors were selected based on education, experience, and training. Self-inspection findings were categorized into critical, major, and other categories.

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

9. Personnel

The company had over 700 personnel with the necessary qualifications and practical experience working in the various departments. Personnel interviewed during the inspection were generally aware of the principles of GMP. An organogram was in place, detailing the company's technical positions and reporting relationships. The quality unit was separate from the production functions. Job descriptions were available and signed by the respective employees. A system for delegating duties was also established.

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

10. Training

The procedure for training plant personnel was in place and reviewed. Trainings were managed in a Learning management system (LMS). The SOP described the various types of training, including onboarding of new employees through induction training, and mandatory ongoing training to be administered once a year according to a defined schedule. Training evaluation was conducted through assessments comprising test questions or verbal assessments. A pass mark of >80% was required to pass the training. Employees were required to be retrained in the event of a prolonged absence exceeding one month. An annual training calendar was in place, covering topics such as data integrity and the culture of pharmaceutical quality. Training for general GMP and data integrity, implemented in May 2025, was discussed. Records for assessment and training materials were reviewed. An annual tracker for employee training attendance was in place and monitored by HR. A separate training record for casual workers in GMP was also reviewed.

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

11. Personal hygiene

The personnel were required to enter the manufacturing facility through the designated changerooms. A gowning procedure for employee entry and exit in core processing areas was in place. The gowning instructions were displayed at the changerooms, and facemasks, shoe covers, hairnets, and gowns were provided. An adequate hand-washing facility was available before entering the manufacturing areas. Training records for employees on hygiene and sanitation practices to be followed were available. A medical examination policy for all employees was available and documented in the corporate SOP. Employees were required to undergo medical checks at the time of recruitment, and thereafter annually. Additionally, all employees working in core areas were required to notify their supervisors in case of a highly infectious disease, open wounds, or lesions on the surface of the body.

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

12. Premises

Generally, the premises were well-maintained and maintained good hygiene. The core manufacturing areas were of smooth epoxy flooring and coved floor-to-wall joints. Electrical fittings were flush with the walls and ceilings. Separate MAL and PAL were provided in the core processing areas, and interlocking doors were installed. Differential pressure was maintained between areas of differing cleanliness, and the readings remained within acceptable limits during the inspection. Environmental conditions, such as temperature and relative humidity, were monitored in core areas where materials were handled.

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

13. Equipment

Equipment observed during the inspection was of appropriate design and well-maintained. Records of equipment cleaning were maintained in E-logs, which listed the cleaning frequency for each piece of equipment. The cleaning procedure and records for the octagonal blender and FBD bags issuance, cleaning, and management records were discussed during the inspection.

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

14. Materials

The warehouse was equipped with two sampling and four dispensing areas. The material receipt area was divided into three separate receiving areas: packing, raw materials, and distribution. The site used a supply chain management (SCM) system that included a bar code reader for material management. The incoming materials were inspected following a checklist, and weights were verified. The pest control and insectocutor were used to control insects. The manufacturer confirmed that 100% sampling was performed for the identification test for all raw materials. The temperature mapping was performed across different seasons, with the temperature maintained at no more than 25 °C. The primary packaging materials were stored at or below 30ºC. The finished product batches for WHO prequalified products were destroyed in October 2023. At the time of the inspection, no sampling or dispensing activity was carried out. The sampling and dispensing areas were equipped with separate MAL and PAL.

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

15. Documentation

A hybrid document system was maintained. Some documents were managed manually, while most SOPs were managed in the electronic document management system (EDMS). The corporate procedure for the preparation, review, approval, release, revision, training, retrieval, and destruction of corporate SOPs was in place and reviewed.

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

16. Good practices in production

Three separate changerooms were provided for operators, supervisors, and visitors. The high-pressure corridor, also known as a positive-pressure corridor, was maintained for the manufacturing of non-sterile products. The temperature and relative humidity were monitored manually. The manufacturing area consisted of eight granulation suites, ten compression machines, and five coating areas. Also, the packaging area was equipped with four (4) blister lines and two (2) bottle lines. Granulation 3 was used for the WHO prequalified products, and the same area would be used for commercializing prequalified products. The granulation, compression, and packaging areas were equipped with separate MAL/PAL.

The inspectors sighted the production and packaging operations and also visited the IPQA laboratory. Both production and QA personnel performed the in-process tests at the frequency specified in the batch manufacturing and packing records.

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 and reviewed sample receipt and management, sample allocation, physical and chemical laboratories, the instrumentation laboratory, and the microbiology laboratory. The quality control laboratory was headed by the QC Manager, who was assisted by various section heads, including the raw material in-charge, the stability in-charge, the finished product testing in-charge, and the microbiology in-charge. The laboratory was equipped with 33 HPLCs (Agilent and Waters with Empower software), two (2) GCs, 1 LC-MS, eight (8) dissolution testers, DSC, TOC, FTIR, UV-VIS, Water by KF, and other equipment and instruments. The samples were manually logged in the register and then also registered in LIMS. The samples were stored below 25°C, and the area was access-controlled. The working, reference, and impurity standards were stored at 2-8 °C in the refrigerator. The finished product analysis was performed on the Laboratory Execution System (LES). The samples were assigned to analysts, who were responsible for sample preparation, loading, and processing. The GLP team performed the calibration of the laboratory equipment, and a schedule for calibration and preventive maintenance was available.

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, ***Ipca Laboratories Limited***, located at ***1, Pharma Zone, SEZ Indore, Pithampur, 454775, Madhya Pradesh, India,*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

All non-compliances observed during the inspection, listed in the full report, as well as those reflected in the WHOPIR, were addressed by the manufacturer to a satisfactory level prior to 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**
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

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**
9789240020900-eng.pdf (who.int)

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