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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	**Immacule Lifesciences Pvt Limited**
Corporate address of the manufacturer	Immacule Life Sciences Pvt. Limited Plot No. 132, 2nd Floor, Sector-82, JLPL, Mohali, Punjab – 140308
Name & address of inspected manufacturing site if different from that given above	Ropar Road, Village Thanthewal, Dist. Solan Nalagarh, Himachal Pradesh 174101 India
Unit/block/workshop number	Sterile product manufacturing (using aseptic processing and terminal sterilization)
Dates of inspection	19-23 May 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Immacule Life Sciences Pvt. Ltd. manufactures sterile (terminally sterilized and aseptically filled) injectable pharmaceutical dosage forms (liquid injection in ampoules, lyophilized vials, and liquid injection in vials) for the domestic and international markets. The manufacturing facility is located in Thanthewal Village, Nalagarh, Solan District, Himachal Pradesh, India. The nearest airport is Chandigarh, 47.6 Km away by road.
General information about the company and site	Immacule Life Sciences Pvt. Ltd was founded in 2012 as a part of the ACME group. It is a Contract Development and Manufacturing Organization (CDMO).
History	This is the first on-site GMP inspection of Immacule Life Sciences by the WHO PQ Inspection Services.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Pharmaceutical quality system - Production, including ampoule manufacturing and packaging - Quality control and microbiology laboratory - Material management, including supplier qualification - Personnel and training - Utilities, including AHUs, purified water system, water for injection, and pure steam
Restrictions	None

Out of scope	The products and areas other than the ampoule line with terminal sterilization for the manufacturing of Sodium Chloride injection and Sodium Bicarbonate inspection were out of the scope of this inspection.
WHO products covered by the inspection	The scope of this inspection was limited to the manufacturing of Sodium Chloride and Sodium Bicarbonate injections as diluents and solvents for Artesunate powder for injection (manufactured by Macleods). **1.** MA152 (Artesunate Powder for solution for injection 60mg + Sodium Bicarbonate 50mg/ml injection + Sodium Chloride 9mg/ml injection) **2.** MA194 (Artesunate Powder for solution for injection 120mg + Sodium Bicarbonate 50mg/ml injection + Sodium Chloride 9mg/ml injection)
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 quality management system was implemented to meet the requirements of the regulatory guidelines (India Schedule M, WHO GMP, EU GMP, MHRA GMP, USFDA GMP). The procedures were described in written SOPs, policies, and other technical protocols. The following software supports the quality management system.

LIMS	CoA generation, Specifications, Standard Test Procedures, Analytical worksheets (master)
EQMS	Investigations, like Change Control, Deviations, Incidents, OOS/OOT
EDCS	SOP issuance and management
LMS	Training management
ERP	Material management, Inventory control
E-log	Equipment operation log
CLEEN	Cleaning validation and cleaning records
DWI	Cleaning details of the equipment
eAPQR	Annual Product Quality Review preparation

The QA was responsible for

- Change control,
- Investigations, like deviations, incidents, quality complaints,
- Self-inspections
- Risk assessment
- Training system
- Product quality reviews
- CAPA management
- Data integrity
- Documentation system
- Batch release of the product
- Vendor approval

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

The Immacule manufacturing facility was dedicated to producing general sterile injectable pharmaceutical dosage forms, including liquid injections (ampoules) and vials (lyophilized and liquid). The scope of this inspection was limited to the manufacturing of Sodium Chloride and Sodium Bicarbonate injections as diluents and solvents for Artesunate powder for injection (manufactured by Macleods). These products were manufactured on an ampoule filling line used to produce other products across various therapeutic areas.

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

3. Sanitation and hygiene

The SOP for receipt, storage, preparation, and usage of disinfectants was reviewed. According to the procedure, seven disinfectants were identified. Upon receipt, disinfectants were tested before being released for use. The disinfection efficacy study was reviewed. Six microbial cultures and environmental isolates were used to perform the study. Different concentrations of disinfectants (as recommended by the manufacturer and those exceeding the recommendation) and contact times were used in the efficacy study. For the microbial cultures, 10^4 CFU was used.

Garments used in Class B/C/D areas: washed and checked on-site in the laundry. Garments used in the CNC areas: service provider laundry. All the garments were visually inspected. The sterilization/washing cycles of the aseptic area garments were limited to 100 and recorded in a logbook.

4. Qualification and validation

The validation master plan (MVP/MVP/22/83, effective date 19/05/2025) provided information on the validation activities carried out at the facility. It covered the qualification/validation approach for facilities, equipment, instruments, utilities, processes, cleaning methods, analytical methods, computer systems, temperature mapping, transportation studies, and media fills.

Process validation for Sodium Bicarbonate injection and Sodium Chloride injection was reviewed. Similarly, cleaning validation and verification were discussed. In general, qualification and validation activities were carried out adequately.

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

5. Complaints

The market complaints were recorded in the E-log system and managed in accordance with SO. Apart from the SOP, the technical agreement between the contract giver and the contract acceptor provided instructions regarding the market complaint. The received complaints were categorized. The category defined the investigation deadlines as follows: critical defect (within 7 days), major defect (within 15 days), and minor defect (within 30 days). The complainant acknowledged the complaints within 24 hours of receipt. The closing (with investigation report) was to be sent out within 30 days. No complaints were received regarding the inspected products.

6. Product recalls

The product recall and the activities related to the recall were essentially the responsibility of the contract giver (Macleods, as the manufacturer and MAH). The partners' related responsibilities were detailed in the Technical Agreement. The events triggering the recall were classified as Class I, II, III, and IV. The recall can be company- or authority-led. No product recalls were recorded for products within the scope of the inspection.

7. Contract production, analysis, and other activities

The inspected products (Sodium chloride and Sodium bicarbonate injections) were manufactured by Immacule, Baddi, as a contract manufacturer. The technical agreement between the parties was in place. The contract covered the following areas: CoA, change control, audits, sample retention, document retention, complaints, recalls, storage and distribution, deviations, and OOS.

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

Self-inspection

According to the procedure, self-inspections were due every 6 months for all departments involved in GMP activities. The audit team consisted of trained and qualified personnel indicated on the official list of auditors. Following the audit, an audit report was prepared highlighting the observations as "Critical", "Major", "Minor", and "Recommendation". The records of the most recent internal audit of the warehouse, conducted by two auditors from QA, were discussed.

Vendor qualification

The vendor qualification process started with an intimation. Based on the information gathered from trial sample testing, questionnaires, and on-site audits (as applicable), the vendors were approved or rejected. The approved vendors (manufacturers) and suppliers were listed on the approved partners' list. Following initial qualification (approval), vendors were requalified every three years, and their performance was reviewed annually. The last re-qualification records of Avantor Performance Material LLC (manufacturer and supplier of sodium chloride) were discussed. The desk assessment was based on a questionnaire.

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

9. Personnel

The up-to-date organizational chart was available, indicating the organizational units and reporting lines. The production and quality functions were separated. The strength of the company was as follows:

Operation (3), QA (74), QC (121), Production (166), Packing (54), Engineering (55), Warehouse (24), IT (8), and Other (82).

10. Training

The training procedure was detailed in SOP/QA/057, E11, 13/11/24. The training system covered the following training forms and topics:

- Induction training of the newly recruited staff
- Initial training on the job-specific technical matters
- Scheduled training on the scheduled topics
- Refresher training on the substantial topics required to be refreshed
- GMP training for the staff involved in GMP activities
- EHS training according to the applicable legislation and as defined by the EHS staff
- Specific training on selected topics
- Awareness training, usually as a consequence of investigation, root cause analysis
- Contract worker training for the temporary staff

The flowchart of the process, as managed by the LMS- Learning Management System, was part of the SOP. The effective and timely execution of the training was the responsibility of the department's training coordinators. The following training records were discussed

- Refreshment training IMC/PD/CR/24/3894
- Training files of a helper, two operators, and a Senior operator

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

11. Personal hygiene

Personnel hygiene

The general personnel hygiene and gowning rules, together with the personnel movement in the controlled areas, were detailed in SOPs:

- Personnel hygiene,
- Entry-exit of grade C areas,
- Entry-exit of grade B areas,
- Personnel behavior in Class aseptic areas,
- Viable and non-viable particle monitoring at product formulation facilities

The entrance to the aseptic processing and sterility testing areas was restricted to staff qualified according to SOP. The gowning qualification consisted of the following steps:

- Training (including theoretical and demonstration)
- Mock monitoring (classroom)
- Gowning in the aseptic change-room with microbiology monitoring (performed in 3 consecutive days)
- Media manipulation.
- Participation in aseptic process simulation (APS)

The qualification is valid for 1 year. The list of qualified personnel was available. The routine personnel microbiology monitoring was due at any time, and personnel were leaving the aseptic areas.

The initial qualification and the last media-fill records of a senior operator were discussed.

- The qualification was initiated by the production.
- The date of the training
- The aseptic gowning and the corresponding microbiology monitoring
- Media manipulation
- Participation in the last media fill

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

12. Premises

The GMP operations were performed in the following premises.

- Block A, Ground floor (Dispensing, Compounding, Sterile filtration, Filling, Lyophilization, Terminal sterilization, Utilities (AHU/PW/WFI/Pure steam)
- Block A, Second floor (Visual inspection, labelling, Secondary packaging)
- Block B, Ground floor (Warehouse (RM/PM/FG),
- Quality control laboratories (chemical and microbiology), Quality Assurance, and stability chambers) were in first floor at Block B
- Block B, Second floor (Warehouse (PM/FG)

The material movement was planned via the shortest route between production stages. The transportation of materials between controlled areas of different classifications occurred through hatches or a double-door autoclave. The personnel flow was controlled by a fingerprint reader.

13. Equipment

General

To ensure satisfactory functioning, equipment and instruments were qualified, calibrated, maintained, and serviced in accordance with the relevant SOPs and protocols. The qualification and calibration dates and due dates were indicated on a label attached to the instrument. The SOPs were available for each instrument and piece of equipment for use, qualification, calibration, and maintenance. The usage records were kept for major and critical equipment.

The main manufacturing instrumentation and its capacity.

- Vial filling and stoppering (Snowbell), 170 vials/min (10 ml)
  Liquide Vials, 2/3/5/10/15/20/25/30/50/100 ml
  Lyophilized vials, 5/6/10/15/20/25/50 ml
- Ampoule filling and sealing (Snowbell), 180 ampoules /min (5 ml)
  Ampoules, 1/2/5/10 ml
- Process sterilizer 1728 L (Machin Fabric)
- Terminal sterilizer 2160 L (Machin Fabric)

Calibration

The calibration activities were executed in accordance with the Calibration Master Plan SOP. The classification defined the frequency of calibration:

- Critical devices: every 6 months
- Non-critical devices: annually

The calibration records of the temperature sensor were discussed.

Water systems

The purified water system capacity: 3 kL/h with a storage tank of 6 kL. The water source was a bore well. The purification process consisted of ultrafiltration, double-pass reverse osmosis (RO), electrodialysis (EDI), and UV treatment. The water is circulated in the loop at ambient temperature. The system is sanitized with hot water at NLT 80 ^{0}C for 30 minutes. The capacity of the WFI generation system was 1kL/h. The WFI was generated from purified water by a multi-effect distillation system. The water was circulated in the loop at NLT 80 ^{0}C. The water sampling procedure was the same for all qualities in the SOP. The quality specification was available for the different water qualities: Purified water and Water for injection. Water system monitoring was conducted as stated in the monitoring program, covering all sampling and user points at a defined frequency.

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

14. Materials

The SOP described the handling of incoming materials. The receipt checklist summarized information on document verification, vehicle verification, physical verification, and the receipt. The supplier was always compared with the approved vendor list. The main shipment data was entered into the E-log and the ERP, where the goods receipt note (GRN) was automatically generated. Upon receipt of the GRN, a sample request is generated for QC. The sampling was performed according to SOP.

The SOP described the material movement in the controlled (classified) areas. The list of utensils transferred through the pass-box was included as an annexure to the SOP, along with the detailed sanitization procedure. The pass boxes were operated and cleaned in accordance with SOP. The transfer of the material through the pass-box was validated. The disinfectant agents were Virosil and IPA with 5 5-minute hold time. The material transfer validation protocol and report of the sterile IPA container in double PE bags (from the Grade C to the Grade B area) were discussed. The autoclavable materials and utensils were transferred to the Grade B areas through a double-door autoclave. The autoclave load and the corresponding operating parameters (receipts) were fixed. 37 autoclave loads were defined, including the minimum and maximum loads. The approved list of users having access to the autoclave and the corresponding user privileges was available. (User privilege matrix for the autoclave

SOP/QA/065-F04 E7, 12/05/25). Users were managed in accordance with the general SOP on user privileges for critical equipment.

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

15. Documentation

The principles of the documentation system and the management of the different documents, such as SMF, Quality Manual, investigations, raw data, layouts, CCS, SOPs, etc., were described in the corresponding SOPs:

- Document request, issuance, and retrieval
- Document control

The procedure for handling the BMR and BPR was reviewed. The batch record request was initiated by Production through the E-DCS system and submitted to QA for approval and issuance. The BMR/BPR was issued for a complete or partial document, as noted from the E-DCS.

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

16. Good practices in production

The detailed manufacturing instructions were available in approved batch manufacturing and packaging record masters. The execution of manufacturing, sampling, in-process control, and other activities during production was recorded in the batch manufacturing records. The manufacturing and quality control facilities and equipment were qualified and regularly monitored to assure the required performance. The corresponding records, randomly selected and discussed, were available in hard copy and electronic form. The inspectors sighted the ampoule washing, raw material staging, compounding, and filling areas. The personnel working in various areas donned gowns according to the classification of their areas. The ampoule filling line was equipped with CIP/SIP.

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

17. Good practices in quality control

The quality control laboratory, located on the first floor of Block B, included a wet lab, an instrumentation lab, a microbiology lab, and other general areas. The laboratory was responsible for testing and release (rejection) of raw material, intermediate, finished product, water, and environmental sample testing in the following sections and facilities:

- Wet laboratory
- Instrument laboratory
- Hot zone room
- Chemical storage room
- Glassware storage room
- Washing room

- Sample collection room
- Stability chambers
- Control sample room

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, **Immacule Life Sciences Pvt Ltd**, located at **Ropar Road, Village Thanthewal, Dist. Solan, Nalagarh, Himachal Pradesh 174101, 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***
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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