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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	**Bliss GVS Pharma Limited**
Corporate address of the manufacturer	102 Hyde Park, Saki Vihar Road, Andheri East, Mumbai - 400 072
Name & address of inspected manufacturing site if different from that given above	Survey No. 43-44, Vevoor Village, Palghar, Maharashtra 401404, India
Unit/block/workshop number	Unit 1500 (solid and semi-solid dosage forms)
Inspection details	
Dates of inspection	19-23 January 2026
Type of inspection	Initial inspection
Introduction	
Brief description of the manufacturing activities	Bliss GVS Pharma Ltd. commissioned Unit 1500 in 2020 to produce tablets, capsules, dry syrup, and sachets. The Unit was expanded in 2024, and a semi-solid facility was added. The site is approximately 115 km from Mumbai International Airport.
General information about the company and site	Bliss Chemicals & Pharmaceuticals India Ltd was incorporated in 1984 and was merged with GVS Labs in 2006 to form Bliss GVS Pharma Ltd. The company has three Units identified as 1200, 1300, and 1500, located on Plot 10, Plot 12, Plot 11, and Survey Nos. 43 & 44 respectively.
History	This is the first PQ Inspection of Bliss GVS Pharma Ltd. The manufacturer was inspected by the EU & USFDA for Unit 1300 and by the EU for Unit 1500.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management system - Personnel and training - Premises and equipment - Production and packaging operations - Quality control laboratory, including a microbiology laboratory - Air handling units - Purified water system
Restrictions	None
Out of scope	Facilities and products other than MA212 and MA213 were out of the scope of this inspection.

WHO products covered by the inspection	Artemether/Lumefantrine Tablet 20mg/120mg (MA212) Artemether/Lumefantrine Tablet 80mg/480mg (MA213)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original, and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
GPT	Growth promotion test
HEPA	High-efficiency particulate air
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non conformity
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

The site had a quality management system (QMS) that incorporated Good Manufacturing Practices (GMP) across all areas of the facility, including manufacturing, packaging, laboratories, warehouses, and other departments. The QA, QC, and production departments reported independently to the Chief Executive Officer (CEO), and both QA and QC Site Heads reported independently to Corporate QA and Corporate QC, respectively. The CQA controls and governs the implementation and operation of the quality system. Some elements of the QMS were assisted by computerized systems such as SAP ECC version 6.0. The following QMS elements were reviewed:

Product quality review/PQR

The SOP for PQR was discussed. The SOP referenced PIC/S, ICH Q10, and WHO TRS 986 Annex 2, and the PQR review was currently performed manually without using SAP. The PQR review included starting materials, critical in-process controls, semi-finished products, finished products, process capability, the quality management system, and other areas. The PQR was performed following the rolling review. A validated spreadsheet was used to calculate process capability. At least 20 batches were required to calculate process capability.

Quality risk management/QRM

The SOP for QRM was discussed. A process flow diagram was part of the procedure. Although various tools were identified in the SOP, only FMEA was used, with no justification. The electronic logbook was part of the SAP system.

Nitrosamine risk assessment

The RA of nitrosamine impurities in Artemether/Lumefantrine tablets was reviewed. Based on feedback from the PQ assessors, the specification was revised to include NDSRI and other nitrosamine impurities. Lumefantrine (for NDMA, NDEA, and NDBA) and the finished product (for NDMA, NDEA, NDBA,

and N-nitroso Desbutyl Lumefantrine) were tested by an outside party, and the results were reported within the detection limit.

The elemental impurities risk assessment report for A/L tablets 20/120 and 80/480mg was reviewed. The RA included reviews of excipients, APIs, and the finished-product manufacturing process. The API manufacturer's declaration was used to conduct the RA. Also, declarations from other vendors and equipment suppliers were used for RA. Based on the RA, no testing was required.

Change control

SOP for change control management described two categories of changes: temporary and permanent. A temporary change was a prospective change applied for a defined, limited period or limited quantity of material/batch, after which the initial conditions were restored, or the change was made permanent through a permanent change control proposal after evaluation. A permanent change was defined as a prospective modification to a product or the process, facilities, automated systems, equipment, documents, and controls used in its manufacture, testing, packaging, storage, release, and shipping. The SOP also provided for the classification of change as critical, major, or minor. The change control SOP was ambiguous regarding risk and impact assessments. It required RA to be carried out before impact assessment, yet impact assessment was structured for the type of change and the corresponding potential areas to evaluate for the impact, e.g., change in manufacturing or testing, facility, new/change in suppliers/vendors, facilities, utilities, equipment, computer systems, and infrastructure.

Deviations

SOP for handling deviations had a scope encompassing deviations from SOPs, batch records, and specifications, as well as unusual/unexpected occurrences during manufacturing, packaging, storage, and QC activities. The deviation details were logged in the SAP. A deviation was defined as a departure from an approved instruction or established standard, or from cGMP, that could negatively impact the quality, integrity, and/or efficacy of the finished product, including unexplained discrepancies. In the impact assessment, a deviation had to be categorized as critical, major, or minor. Investigations were conducted by a multi-functional team and reported to the Head of QA.

Incidents

In the incident reporting and investigation SOP, an incident was defined as an unplanned event that occurs in nonconformance with a design system or procedures at any stage of analysis of material or sample. The scope of the SOP indicated that it was applicable only to the QC laboratory during testing of materials with tiered specifications (e.g., dissolution stages S1, S2, and S3; content uniformity; water conductivity tests; instrument calibration qualification). Incidents were required to be investigated to identify the cause of the error. Hypothesis testing and resampling could be involved. Incidents were not related to deviations. An incident could lead to an OOS investigation. The incident log was maintained in SAP. In 2025, there were 184 incidents across the categories of equipment, materials, method, man, and utilities. Trend analysis reports were prepared quarterly and made available.

CAPA

The CAPA SOP and the Investigation SOP were reviewed. The tools for root cause analysis were stated as brainstorming, 5-Why, and fishbone diagram. An investigation plan sheet indicated a cross-functional team (CFT) of four people: three from QA and one from production. An investigation plan was drafted,

covering 6 areas for investigation. Corrective action, preventive documentation, and tracking were performed in SAP.

Management review/MR

SOP for MR was reviewed. Top management (the CEO and the directors) chairs the half-annual MR. Site Heads conducted quarterly MRs and ensured the implementation of actions from prior MRs. The list of quality objectives approved by the CEO included objectives related to compliance, quality management, efficiency improvement, data integrity, and resource competence. There were only four quality objectives related to PQS, namely OOS, marketing complaints, deviations, and change control. The MR report included agenda items, discussion points, decisions, actions, responsible person(s), target completion date, and status.

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

Bliss GVS Pharma Limited has a multi-product manufacturing facility that produces finished pharmaceutical products of various therapeutic categories and dosage forms. In general, the manufacturing facility was well-maintained and adequately equipped with sophisticated equipment. In a number of manufacturing areas, equipment were connected with a vacuum transfer system to transfer in-process materials from one stage to another under closed conditions.

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

3. Sanitation and hygiene

The facility observed a high level of sanitation. There were adequate change-room facilities for gowning, handwashing, drying, and disinfection. The training curriculum provided specific training for each employee on adhering to personal hygiene and clothing requirements outlined in the standard operating procedure, as well as to the pictorial entry and exit procedures displayed in the respective change rooms.

4. Qualification and validation

The Validation Master Plan (VMP) was prepared for 2 years, covering 2025-2026, and included activities such as process validation, computerized system validation, qualification/requalification, and other areas. The requalification frequency was described in the VMP. Equipment requalification was performed every 3 years for critical equipment; AHUs were requalified annually and biannually. Temperature mapping covering three seasons was completed for various storage areas. The contracted services were used for the qualification and requalification of equipment and areas.

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

5. Complaints

SOP for complaints was reviewed. The site QA manager was responsible for recording complaints received. Complaints can be received by a complainant (any regulatory agency, distributor, logistics agent, retailer, stockist, field staff, customer, doctor, or patient) through letters, emails, faxes, or telephone calls. Acknowledgment of receipt of a complaint was specified to be within 3 days. Complaints were categorized as critical, major, and minor. The preliminary investigation report was expected within 3 days. The investigation team comprised the QA team and the concerned department. After closure, trend analysis was required. On the product information leaflets, there was a statement that if you have any questions about this product or would like to report an adverse drug reaction (ADR), contact us by phone/email. All complaints received were recorded on the market complaint investigation report, which required detailed sample information.

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

6. Product recalls

The product recall SOP stated that the site QA Head was responsible for initiating the product recall proposal and for reviewing classification, recall depth, and CQA approval. The recalls were classified as Class I, Class II, and Class III. Depth of recalls included up to the consumer or user levels. Recalls could be triggered by any regulatory agency (statutory recalls) or by the manufacturer (voluntary recalls). No statutory recalls ever happened. One voluntary recall (initiated by Bliss GVS) took place in 2025

7. Contract production, analysis and other activities

No manufacturing processes or steps for the finished products were performed off-site. Some analytical testing was outsourced to competent laboratories. The Analytical Research and the QC departments were responsible for identifying and evaluating new external testing laboratories. These laboratories were required to have the necessary infrastructure, facilities, and equipment to carry out the required activities. A facility audit was required to qualify external testing laboratories. Quality agreements were then established between Bliss GVS Pharma Ltd. and the approved testing laboratory, defining the quality roles and responsibilities of both parties to ensure compliance with standards.

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

The self-inspection SOP was reviewed. A self-inspection checklist was used. The self-inspection schedule for 2025 indicated that each department was to be audited twice. A list of qualified internal auditors included 18 self-inspection auditors. Classification of nonconformances as critical, major, or minor was used.

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

9. Personnel

A current organizational structure had been approved by the Plant (Site) Head. There were adequate number of personnel with the necessary qualifications and practical experience. According to the company presentation, there was a total of 466 employees, of which 169 were in OSD production, 50 in semi-solid production, 46 in QA, 100 projected in QC, 29 in the warehouse, 48 in engineering, 5 in IT+SAP, 5 in technical transfer, learning and development, 3 in human resources, and others. Duties and responsibilities were documented in up-to-date, controlled job descriptions (JDs).

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

10. Training

Implementation of the SOP for training of personnel was primarily the responsibility of the Learning and Development (L&D) Team, which was part of the HR department. The SOP provided for induction training, on-the-job training, technical and functional skill assessment, evaluation of training, and training effectiveness check. Training records were kept for each individual employee. Post-training questionnaires were used, with a pass mark of 80%. Effectiveness checks were conducted randomly, not for each individual training course/program. A practical effectiveness check can be carried out at any time by a QA person and L&D personnel. The training program of one of the analysts in the QC department was reviewed. It provided a job role followed by the topics relevant to that. For analysts in the stability studies, training was required as follows: on-the-job training protocol (indicating the required topics, document, delivery mode [e.g., instructor-led or self-study], training date, training duration, trainer's signature and date, trainee's signature and date), evaluation method, and evaluation outcome. The training curriculum had Part A for mandatory training, Part B for retraining required, Part C for functional training, and Part D for retraining for functional training. After this, QC personnel undergo analyst qualification. One of the on-board trainings was in data integrity. Training materials (PowerPoint presentations) for data integrity were available. Evaluation of the training was determined by administering a structured questionnaire after the training.

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

11. Personal hygiene

Personnel hygiene procedure provided for grooming, illness, cuts and burns, smoking, eating and chewing, and frisking. Each employee was trained in these areas. Employees with open lesions or exposed body surfaces, cuts, abrasion or burns were not allowed in the manufacturing areas. It was stated that the face biometrics access system did not allow an employee to enter a changeroom if their body temperature exceeded 38°C, which could be due to flu-like symptoms or infectious diseases. Those with diarrhea and vomiting were also prohibited from entering controlled areas (cleanrooms).

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

12. Premises

The layout of the manufacturing facility was discussed. The manufacturing facility spanned two floors, with all manufacturing activities carried out across small-, medium-, and large-scale facilities. The ground floor (GF) houses small-, medium-, and large-scale manufacturing areas, a warehouse, and a packaging area for medium- and large-scale products. A lift was used to transfer materials from GF to FF. The first floor (FF) houses QC, QA, documentation storage, the stability section, control samples, BMS, the secondary water system, and the ointment manufacturing area. The manufacturing area, including the primary packaging section, was classified as ISO 8. Secondary packaging was conducted in CNC. For pressure cascading, the corridor was overly pressurized relative to airlocks in low-RH areas only. The core processing areas were maintained at negative pressure relative to the corridor (35 versus 20/25 pascals). The cleaning equipment, change parts, dies/punches, and accessories storage rooms were designed to 45 pascals relative to the adjacent area.

The premises were equipped with several air-handling units, a purified water system, a compressed-air system, and other utilities to support the manufacture of pharmaceutical products.

13. Equipment

The manufacturing facility was equipped with sophisticated equipment and instruments. The equipment were located, designed, constructed, and maintained to suit the operations to be carried out. Equipment found inside the granulation area were installed and operated to minimize the risk of contamination. The granules were charged to the compression machine via the vacuum transfer system, whereas the compressed tablets were manually charged for blister packing. Equipment were cleaned between the batches of the same product and between different products following Type A and B cleaning procedures. As such, non-dedicated equipment were used for the manufacturing of products of different therapeutic areas. The laboratory equipment and instruments were suited to the testing procedures undertaken.

14. Materials

The warehousing areas were inspected. Access to the warehouse was through a limited-access biometric system, via a change room where wearing appropriate protective gowning was required. There were two separate receiving bays, one for starting materials and the other for packaging materials. Starting materials were passed through a dedusting tunnel and were then placed on plastic pallets. The goods received note was prepared in SAP, and a barcode reader was used to capture material particulars from the manufacturer's label and indicate the location (shelf number) of the materials in the warehouse. There were separate areas for storing raw materials, primary printed packaging materials, PVC reels, and secondary and tertiary packaging materials. Control of starting materials and packaging materials, including quarantine, under-testing, release, and rejection, was managed through SAP and the bar-coding system. Sampling was carried out for each container of active raw materials and $\sqrt{n+1}$ for excipients. Two sampling rooms were available, each with a separate entry for man and materials. There was also a separate sampling and dispensing room for solvents, where sampling was automated. A separate room for storing rejected or expired materials was also available. The status of each material can be checked at any time by scanning the label's barcode. A washing area for small equipment was located between the two

sampling rooms. Stainless steel sampling rods and spatulas were well wrapped and status-labeled "Cleaned". Temperature and relative humidity were controlled electronically by the BMS. Room pressure differentials were also controlled electronically by the BMS. Material retest dates were entered in the SAP system, with a 1-year retest policy for APIs and a 2-year retest policy for excipients. The finished product inventory was also managed in SAP. Issuance of released (unrestricted) materials for production (dispensing) was managed in SAP on a FIFO/FEFO basis.

The vendor qualification procedure was reviewed. The suppliers were qualified for APIs, excipients, and packaging materials. Suppliers were provisionally qualified for 6-month before full approval. The procedure did not specify recall and destruction of batches sourced from provisionally approved suppliers due to quality and safety issues.

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

15. Documentation

Documents such as change control management, SOP management, retention sample management, stability management, vendor qualification, specifications, standard testing procedures (STPs), QRM, OOS, OOT, deviations, incidents, CAPA, artwork management, and preventive maintenance were handled in the SAP system. QC recorded finished product results in the SAP system, and QA finally released the batch. Paper-based files, mainly containing records, were kept by QA in portable mobile racks with a computer-controlled filing-tracking system.

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

16. Good practices in production

The inspector visited the production areas, including small-, medium-, and large-scale areas. Adequate gowning instructions were provided before entering the manufacturing areas. Personnel-specific gowning was provided, each labeled with the person's name. The shoe cover, 2-piece gowning, beard mask, and hairnet were available. 70% IPA was used to sanitize hands before entering the clean corridor. In general, the facility was well-maintained, with adequate lighting and cleanliness. Face recognition and biometric access were provided for the personnel working in the manufacturing areas. The pressure differential was monitored digitally and manually throughout the facility. Manufacturing equipment of varying capacities was used in small, medium, and large areas. The WHO PQ products in question were manufactured in medium and large areas. The integrated granulation lines from Glatt were used, and products were handled in a closed system. The in-process materials were transferred via a vacuum transfer system from one piece of equipment to another. Metformin 500mg tablets were being produced in the compression area. The 32-station compression machine was used for WHO PQ A/L 80/480 tablets. Identical machines were used in medium and large areas. The large scale manufacturing area has two blister lines, one sachet line, and one bottle line. Bliss Electronics Tablet Application (BETA) was implemented in 2023 to display the status of areas, equipment, and products manufactured in various areas. The EMS and System Application and Data Processing (SAP) were integrated and displayed on BETA. The equipment and area logbook for GF156, used for the production of Metformin 500/850/1000mg tablets, was reviewed.

The manufacturer confirmed that hose pipes, transfer lines, and finger bags were dedicated to specific products. Type A (dry cleaning) and Type B (wet cleaning during product changeover) cleaning procedures were applied. If more than 72 hours had lapsed after the type B cleaning, a thorough cleaning was required. The ACG Conserve 360 bin-washing station was used to wash and clean bins.

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 inspectors visited the QC laboratory. The laboratory had 82 staff members working across sections, including physical, chemical, instrumentation, stability, microbiology, and good laboratory practices. The laboratory was equipped with 20 HPLCs, 1 UPLC, 2 GCs, 5 dissolution testers, 1 Malvern Mastersizer, and others. Samples of raw materials, semi-finished products, finished products, and for the ongoing stability program were received into the laboratory through a static passbox and stored in separate lockable stainless steel cabins. The SAP was used for logging incoming samples, whereas allocation was performed manually. The SAP was not interfaced with any instruments, including analytical balances. The results were reported in the SAP. The following lab equipment were connected to the LABX 2019 version 10.0.1.747 software that could generate print-outs: analytical balances, pH meter, conductivity meter, auto-titrator, melting point, and UV refractometer. The QC laboratory was neat, orderly, and well-maintained.

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, ***Bliss GVS Pharma Limited***, located at ***Survey No. 43-44, Vevoor Village, Palghar, Maharashtra, 401404, 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-eight 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. Fifties 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
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