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Prequalification Unit-Inspection Services
WHO PUBLIC INSPECTION REPORT
Finished Pharmaceutical Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Shanghai Dahua Pharmaceutical Co., Ltd.
Corporate address of manufacturer	No. 3503 Changzheng Farm Road, Chongming District, Shanghai, P.R. China
Inspected Site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit / block / workshop number	Production block: Line 1 and Line 2
Inspection details	
Dates of inspection	18 – 22 November 2024
Type of inspection	Routine inspection
Introduction	
Brief description of the manufacturing activities	Production, quality control and product release of Levonorgestrel Implant
General information about the company and site	Shanghai Dahua Pharmaceutical Co., Ltd. was founded in 1991. Dahua manufacturing site is located in Chongming district, a suburb of Shanghai. According to the company, the site has not produced any other new products except for the levonorgestrel silicone rod (II) in the past 10 years.
History	The site had been inspected by WHO several times. The product was PQed in June 2017. The last WHO inspection was held in October 2022. The site is regularly inspected by local authorities。
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Quality management system • Production block: Line 1 and Line 2 • QC including chemical and microbiological laboratories. • Warehouse for stating materials and finished products. • Water system
Restrictions	The inspection was restricted to the production of the product listed in the WHO PQ programme.
Out of scope	N/A
WHO products numbers covered by the inspection	RH028 Levonorgestrel Implant 75 mg per rod (150 mg in total)

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
NCA	National control authority
NCL	National control laboratory
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
PUPSIT	Pre-Use Post Sterilization Integrity Testing

PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RABS	Restricted access barrier systems
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

A documented system for quality assurance was established, with procedures covering key quality elements in place. The Quality Department was divided into QA and QC and were separate from the Production Department. Operations were specified in written form and critical GMP requirements were essentially being met. The procedures reviewed and discussed during the inspection were generally of an acceptable standard.

Annual Product Quality Review (PQR)

The SOP for PQR was available. The procedure provided for annual review of different quality aspects of the products including API, excipients and packaging materials quality, finished product quality, stability testing, deviations, CAPA, changes, OOS/OOT, validation and qualification, contract manufacturing and control, environmental monitoring, supplier's qualification including audits, review of quality risk, and pest control etc. The procedure included provisions for statistical process control including calculations of different process capability indices. The instruction in the procedure for the rolling review on an annual basis (from January to December) with finalization and approval of the PQR was set for the end of the first quarter of the subsequent year at the latest.

The 2022 and 2023 APQRs for Levonorgestrel Implant 75 mg per rod (150 mg in total) were reviewed.

Quality Risk Management

The SOP "Quality risk management procedure" was verified. Quality risk management methods and tools were included such as failure mode and effect analysis (FMEA), risk ranking and selection, statistical tools, etc. The RPN acceptance criteria for quantitative risk assessment was defined.
The QRM plan for the product RH028 was available. The quality risk evaluation report of Line 2 was reviewed and found acceptable in general.

Contamination Control Strategy

A contamination control strategy (CCS) for the production process of RH028 was available as per the SOP for contamination control strategy.

Management review (MR)

The SOP for MR was in place. MR meetings were conducted once every year with the participation of senior management. The last two MR meetings conducted in January 2023 and January 2024 were checked. The agenda of the meeting included update on legal and regulatory references, KPIs, internal and external quality audit, CAPA, deviations, OOS, and change control. Recommendations from MR meetings were managed using CAPA procedure.

Change control (CC)

Adequate change control procedures were in place. Changes were classified as critical, major or minor. Among all CCs, the most significant change has been the introduction of Line 2, a new production line to the existing production block. The relevant risk assessment report was checked. The company has acquired automated equipment installed in Line 2. The URS, protocol and report of DQ, IQ OQ/PQ for Equipment were checked and discussed.

Deviations

The SOP for deviation handling was in place. Deviations were classified into three levels: significant, major and minor. Several deviations were selected for in-depth review.

Corrective and Preventive Actions (CAPAs)

The SOP "CAPA management procedure" was checked. The procedure was applicable to but not limited:

- Authorities' inspections
- Self-inspection
- Customer audits
- Deviations
- OOS/OOT
- PQR
- Complaints
- Returns/recalls

The CAPA register was maintained. CAPAs were trended annually. Examples of CAPAs were reviewed.

OOS and OOT

The SOP for OOS/OOT handling was checked. OOS&OOT register was maintained. Examples of reported OOSs were checked.

Product release

The SOP for product batch release was in place. The SOP provided for process flow of the batch release starting with receipt and review of the batch records by QA followed by review of the same by QP and make decision for batch release. One QP was appointed who also delegated the responsibility for batch release one additional QA staff. Batch release sheet was also attached to the SOP and included review of

production records, equipment and facility, OOS, QC results, changes, deviations, data integrity, audit trail etc. followed by conclusion, approval and release statement.
No batches were rejected in 2024.

Data Integrity management
The SOP "Data integration management" was checked. The risk assessment for data integrity related to computer systems was presented and discussed. The access and privileges specified in the procedure of "Computer System" were verified. The data management in the standalone IR equipment was checked.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources with adequate premises, equipment and utilities were provided for the current operational level of FPP activity. Manufacturing processes were generally adequately defined. The manufacturing processes follow procedures as defined and documented in the BMRs and BPRs.

3. Sanitation and hygiene

Personnel hygiene requirements were documented in SOP. The requirements for entry cleanrooms were documented, including pictorial drawings in change rooms. Staff observed in these areas were dressed in appropriate protective clothing.

4. Qualification and validation

Process Validation (PV)
The annual validation master plan of RH028 2024 indicated three batches for the PV.
The process validation protocol and report for production of RH028 at line 2 were reviewed. The PV covered the operations from processing of the raw materials through to primary packaging. Sterilization process validation remained the same since the last WHO inspection in general. The last PQ of the sterilizer was performed in 2024 as per the report.

Cleaning validation
The SOP for cleaning validation was in place. The SOP provided for a minimum of three consecutive batches for CV and the acceptance criteria were defined. The cleaning validation report approved in July 2023 was reviewed.

Computerized system validation
The SOP for computerized system validation was in place. The SOP provided for categorization of computerized systems into four categories namely operational system, standard software package, software with additional functions, and tailored software solutions. Periodic review of computerized systems was required to be performed. A list of computerized systems used at the site was available.

The CSV of the document management system (DMS) was briefly reviewed. In addition, the CSV of the software of the sterilizer including the protocol and report executed in June 2023 was reviewed.

The CSV of LabSolution® was utilized for HPLC instrument in QC laboratory. The OQ report of the software was checked.

5. Complaints

The SOP "Customer complaint handling procedure" was checked. The QA personnel was responsible for handling the complaints. Complaints were received by the marketing department, QA or pharmacovigilance department. A final decision was QP's responsibility. Complaints were classified into Critical, Major or Minor. Consideration was given to whether other batches were also affected, and recall should be initiated. Complaints registered in 2024 and in 2023 were checked and discussed.

6. Product recalls

The SOP "Product recall procedure" was checked. Recalls were classified as:

- Class 1 – recall initiated within 24 hours.
- Class 2 – recall initiated within 72 hours.
- Class 3 – recall initiated within 5 working days.

There was no product recalls reported since last inspection. According to the SOP mock recall should be performed periodically. The last mock recall was checked.

7. Contract production, analysis and other activities

No manufacture was contracted out.

The SOP "Contract laboratory standard operation procedure" were available. An approved list of contract laboratories was presented. The on-site audit or desk assessment of contract laboratories was performed following the SOP.

"The contract testing agreement" between Shanghai Dahua Pharmaceuticals Limited and a contract testing laboratory was checked and found to be acceptable.

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

Self-inspection

Self-inspection was not checked in detail due to the time constraints.

Vendor approval

The SOP "Supplier management" was checked. It explained:

- New supplier approval
- Qualified supplier confirmation
- Supplier classification and coding
- Quality Agreement
- Regular audit,
- Supplier Evaluation
- Supplier complaint
- Supplier disposal
- External auditor qualification

According to the SOP, suppliers were classified as Critical and Other suppliers. The approved supplier's list was available. SOP specified two types of audits i.e. on-site and desk assessment depend on criticality of the material. The supplier's audit schedule for 2023 and 2024 was checked.

9. Personnel

Dahua had an adequate number of personnel with the necessary qualifications and practical experience, job descriptions were available. The number of personnel employed at the site was 104 at the time of inspection.

The personnel were appropriately qualified and adequate training was conducted. The authorized person was nominated and was responsible for compliance with technical or regulatory requirements related to the quality of finished products and the approval of the release of the finished product for sale or supply.

10. Training

Human Resources Department planned and conducted annual employee training according to "Standard Management Procedure for Employee Training". The training plan 2024 was checked. QA department performed training assessment. Each department provided its own specific training related to its job skills, standard operating procedures, GMP guidelines and applicable regulations.

11. Personal health and hygiene

Premises and equipment in the FPP production area were maintained at an acceptable level of cleanliness at the time of inspection. Sanitation of clean areas is performed frequently in accordance with the SOP. Personal and the facilities for sanitation and hygiene established on the site appeared acceptable.

12. Premises

The buildings used for production, quality control laboratories, storage and administration were identified and documented. The buildings were dedicated to the manufacturing and quality control of Levonorgestrel Implant product.

Storage areas

Warehouses for starting materials, primary packaging materials and finished products were briefly visited. Storage areas had acceptable capacity for the current range of products being handled. Segregation was provided for the storage of rejected, recalled, or returned materials or products. The environmental conditions of T & RH were controlled and monitored. The temperature mapping was checked and discussed.

HVAC system

The SOP for HVAC management and SOP for environmental monitoring were established. The procedures specified the requirement for environmental monitoring and qualification/requalification of the system. The OQ and PQ protocol and report of the HVAC for RH028 line 2 were reviewed.

Compresses air system

Compressed air was used in operations of Line 1 and Line 2. The same compressed air generation system served both lines. The design of the compress air system and compressed air's specifications and quality testing were checked and discussed.

Nitrogen system

The quality standard for nitrogen generation system was reviewed. The testing frequency and testing results of the nitrogen were checked.

Water System

The water system located in the production block was visited. The PW was produced by double ROs followed by EDI with one generation system and two distribution loops in ambient temperature. WFI was produced from PW by distillation columns and a condenser to collect WFI. P & ID of the water system was available. 316L stainless steel was utilized for pipes and vessels. The PW and WFI system appeared to be of suitable design for their intended use and maintained under acceptable control in general. The sanitization of loops was performed regularly. The following procedures were reviewed:

- "PW system operation procedure"
- "Cleaning and disinfection of water system"
- "Processing water sampling and monitoring"

The 2023 PW annual review was checked. The alert limit and action limit of PW microbiological monitoring were specified.

13. Equipment

Design and construction

Equipment installed in the production workshops was dedicated to the Levonorgestrel Implant and each piece of equipment had a unique identification number. The equipment viewed appeared to be of suitable design and construction for the allocated process in general.

Equipment maintenance and cleaning

The equipment viewed during the inspection appeared to have been suitably maintained and in good condition. Cleaning procedures and records were available for each item of equipment.

Equipment qualification

The qualification of automated equipment of Line 2 was reviewed, included but not limited to,

- Automated sealing machine
- Automated cutting machine
- Automated primary packing machine

14. Materials

Incoming materials and finished products were quarantined after receipt until released for use or distribution. Status of raw material was indicated, with respect to material under quarantine, approved, and retest etc.

Starting material, packaging material and FPPs were stored in different warehouses under the specified conditions. The warehouses were visited during the inspection. The material codes and locations for starting material and finished goods were spot checked.

The raw material warehouse was equipped with a sampling booth under LAF. The sampling procedure for raw materials, and the sampling and cleaning logbook were checked. A secured area for return and rejected materials were in place.

The space for finished Product warehouse appeared adequate. The records of a released product batch stored in the warehouse was checked and discussed.

15. Documentation

In general, documentation was designed, prepared, reviewed and distributed according to a documented procedure. Approved, signed and dated testing procedures and specifications were available for starting and packaging materials and for finished products.

The documentation system was managed by a computerised system controlled by QA department. The system was validated. The following procedures were checked.

- "Standard Management Procedure for Documentation" which defined the SOPs' initiation, revision, review, approval, obsolete and distribution. The document version update and version control were discussed.
- "Archiving SOP" described the retention time of documents.

Batch numbering system and batch production records

A Batch numbering system was in place and managed according to the SOP "Product manufacturing date, batch number and expiry date management procedure". Batch manufacturing records (BMRs) were retained for each batch processed. The BMRs of Levonorgestrel Implant were checked and discussed.

16. Good practices in production

The production of levonorgestrel implant was in operation at the time of inspection. The production workshop was visited including Line 1 and Line 2 for all processing steps. The manufacturing processes were performed and recorded according to instructions in the batch production records. Manufacturing records of the products under processing were spot checked. The production operations at new production line were observed.

Reworking was not allowed. Reprocessing was managed according to SOP for reprocessing.

17. Good practices in quality control

The QC function was independent of other departments. The QC laboratories were separated from production areas. QC laboratories including the physicochemical laboratory and microbiology laboratory were visited. The microbiology laboratory was segregated from the physicochemical laboratory.

Sample receiving and distribution

An access-controlled area for sample receival was available. Sample register and the information for receiving and distribution were checked. The traceability of raw data was available in the sampling records.

Testing of starting material and finished products

The procedure for testing and release of raw material and procedure for bulk and finished product release procedure were in place. Pharmacopeial reference standards were used for analysis. Reference standards were stored in a fridge under adequate control.

Retention samples
Retention and retained samples were kept in a secured and temperature-controlled room. The retention sample register and samples of each batch were kept. The time and quantities of retention samples to be kept were defined. The annual check for retention sample was verified.

Stability study
A documented programme was designed to monitor the stability characteristics of products. Stability samples were stored in containers that simulate the market container. Stability chambers were available for accelerated and for long term stability studies. Samples in the chambers were seen well organized. Stability chambers were equipped with alarm system. T and RH in chambers were recorded on-line and checked daily.

Instrumentation
The company has adequate numbers of instrument and equipment for QC laboratories. The records and logs were adequately maintained. Status labels were attached to equipment and found acceptable. Calibration status and dates were acceptable. QC HPLC, GC and UV chromatographic analysis was operated and controlled with software with access control, audit tracking and data storage and back up functions. The IR was standalone, and the IR testing data management was spot checked.

Microbiology laboratory
Microbiological laboratory was visited during inspection. Separate rooms were provided for microbial limit tests (MLT), media preparation, media sterilization, media incubation, endotoxin tests (LAL) and sterility test.

The media for testing and environmental monitoring were prepared in-house. Sterility test was carried out in an isolator. No sterility test failure was reported. Sterility testing validation protocol and report were reviewed. The SOP for sterility testing of the product was checked and discussed.

The standard management procedure for environmental monitoring of clean areas and the test results was spot checked. No excursion was recorded.

Disinfectant solutions
The SOP for disinfectant was in place. It provided for preparation of the disinfectant including the sterile filtration. The records of the disinfectant preparation, filtration and filter integrity were spot-checked.

Part 3	Initial conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***Shanghai Dahua Pharmaceutical Company*** located at ***3503 Changzheng Farm Road, Chongming District, Shanghai, China*** 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 GMP 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://www.who.int/publications/m/item/trs986-annex2

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
   https://www.who.int/publications/m/item/annex-2-trs-957

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.
   Short name: WHO TRS 1010, Annex 9
   https://www.who.int/publications/m/item/trs1010-annex9

4. 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
   https://www.who.int/publications/m/item/annex-3-trs-1033

5. 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://www.who.int/publications/m/item/annex-4-trs-929

6. 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. 957, Annex 1
   https://www.who.int/publications/m/item/trs957-annex1

7. 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://www.who.int/publications/m/item/trs957-annex3

8. 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://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation, and air-conditioning 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://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

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://www.who.int/publications/m/item/trs943-annex3

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://www.who.int/publications/m/item/trs961-annex2

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://www.who.int/publications/m/item/trs981-annex2

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://www.who.int/publications/m/item/annex-3-trs-981

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
https://www.who.int/publications/m/item/tr961-annex14

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://www.who.int/publications/m/item/trs1019-annex3

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
https://www.who.int/publications/m/item/trs992-annex4

19. 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://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

20. 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
https://www.who.int/publications/m/item/trs992-annex5

21. WHO Recommendations for quality requirements when plant – derived artemisinin 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/trs-992-annex-6

22. 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
https://www.who.int/publications/m/item/annex-4-trs-1033

23. 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
https://www.who.int/publications/m/item/trs966-annex10

24. 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***
https://www.who.int/publications/m/item/trs1010-annex10

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
https://www.who.int/publications/m/item/annex-2-trs-1033

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
https://www.who.int/publications/m/item/trs-1025-annex-6

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/m/item/trs-1025-annex-3-water-for-injection

27. 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/m/item/trs1025-annex4

28. Good trade and distribution practices for pharmaceutical starting materials. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 6.
Short name: WHO TRS No. 996, Annex 6
https://www.who.int/publications/m/item/annex-6-trs-996