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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
WHOPIR
Finished Product Manufacturer

Part 1	**General information**		
Manufacturers details			
Name of manufacturer	**Guilin Pharmaceutical Co Ltd - OSD**		
Corporate address of manufacturer	Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd., Building A, No.1289 Yishan Road, Shanghai 200233, P.R. China		
Inspected site			
Name & address of inspected manufacturing site if different from that given above	Guilin Pharmaceutical Co Ltd - OSD, No 43 Qilidian Road, Guilin, Guangxi, 541 004, China		
Unit / block / workshop number	OSD Workshop I: Tablets and Capsules		
Inspection details			
Dates of inspection	11-15 September 2023		
Type of inspection	Routine GMP inspection		
Introduction			
Brief description of the manufacturing activities	Guilin Pharmaceutical Co., Ltd. is engaged in the manufacturing of various finished product dosage forms including tablets, capsules (soft capsules, hard capsules), injectables (powder for injections and small-volume parenteral (SVP) injections) and active pharmaceutical ingredients. For the manufacturing of non-sterile oral solid dosage (OSD), the manufacturer has three workshops located in the same building. The tablets and capsules for WHO PQ program and other products for different markets were manufactured in OSD workshop I.		
General information about the company and site	Guilin Pharmaceutical Co., Ltd. is a subsidiary of the Shanghai Fosun Pharmaceutical (Group) Co., Ltd since 2003. All products manufactured on site, except the antiviral, application number CV023, Molnupiravir capsules 200mg have received registration with the National Medicines Regulatory Authority (NMPA, China). Since the previous WHO inspections (October 2021~ August 2023), several major changes have been executed included new product application, changes related to formula and process, specification, premises, equipment, facility and company organization structure etc.		
History of	**Authority**	**Dates of inspection**	**Scope of inspection**

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previous regulatory inspections: 2021-2023	WHO	2021.09	API-I, API-II, OSD-I, INJ-I, INJ-II, INJ-VI
	Provincial FDA (GuangXi FDA)	2021.10	OSD-I, INJ-I, INJ-II, INJ-VI
	Provincial FDA (GuangXi FDA	2022.07	OSD-I, INJ-I, INJ-II, INJ-VI
	Provincial FDA (GuangXi FDA)	2023.07	OSD-I
	US FDA	2023.08	OSD-I

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document Review included but not limited to:** - Quality management system - Documentation system - Validation and qualification **Site areas visited:** - Production block OSD-I - Previous Penicillin FPP production block - Previous Penicillin API production block - Quality laboratory - Warehouses - Purified water system - Waste Management Storage Area
Restrictions	The inspection was restricted to the production of the product listed in the inspection scope.
Out of scope	The PQ inspection was limited to workshop OSD-I with the two OSD workshops (OSD-II, OSD-III) out of the scope of this inspection. Due to the WHO Notice of Concern (NOC) issued to the BE site, Accutest, Navi Mumbai the following prequalified products were suspended and out of scope of the inspection: 1. MA153 Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg 2. MA154 Artemether/Lumefantrine Tablet, Dispersible 40mg/240mg 3. MA155 Artemether/Lumefantrine Tablet, Dispersible 60mg/360mg 4. MA164 Artemether/Lumefantrine Tablet 20mg/120mg 5. MA165 Artemether/Lumefantrine Tablet 80mg/480mg
WHO products numbers covered by the inspection	1. MA083 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg 2. MA084 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg 3. MA085 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg 4. MA113 Pyrimethamine/Sulfadoxine Tablet 25mg/500mg

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	5. MA116 Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) dispersible Talets 12.5mg/250mg + 76.5mg 6. MA117 Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) dispersible tables 25mg/500mg + 153mg 7. MA131 Dihydroartemisinin/Piperaquine (phosphate) Tablet, Film-coated 40mg/320mg 8. MA139 Dihydroartemisinin/Piperaquine (phosphate) Tablet, Dispersible 40mg/320mg 9. MA140 Dihydroartemisinin/Piperaquine (phosphate) Tablet, Film-coated 80mg/640mg 10. MA141 Dihydroartemisinin/Piperaquine (phosphate) Tablet, Dispersible 20mg/160mg 11. MA151 Dihydroartemisinin/Piperaquine (phosphate) Tablet, Film-coated 60mg/480mg 12. MA157 Dihydroartemisinin/Piperaquine phosphate Tablet, Dispersible 30mg/240mg 13. MA178 Pyrimethamine/Sulfadoxine Tablet, Dispersible 12.50mg/250mg 14. MA179 Pyrimethamine/Sulfadoxine Tablet, Dispersible 25mg/500mg 15. CV 023 Molnupiravir Capsules, hard 200mg (**under assessment/Applicant Shanghai Fosun Pharmaceuticals**)
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

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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
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
SMP	Standard management procedure
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

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Senior Management demonstrated a commitment to the QMS by granting adequate resources to implement, support and manage the QMS. The Organogram identified the quality and production department operating under different leadership with the Qualified Person reporting into Head of Quality. Job descriptions were available addressing inter alia responsibility, qualification, and experience. The Vice President (Head of Quality) was overall responsible for the management of product quality.

Management review

Management review was performed following the documented procedure. Quarterly management review meetings for discussion of quality matters i.e., audits, complaints, recalls, APQR's, production were conducted. Management meetings were attended by heads of the various units, with minutes and attendance register available and kept. Meeting minutes of July 2023 were reviewed. Trend Analysis was performed for OOS, Deviations and reported at quarterly management committee meetings.

Product release

The SMP for product release was reviewed and discussed in relation to the overall final responsibility for the batch release of finished products.

Change control

The SMP for change control was briefly discussed. During the inspection change controls executed were reviewed and effectiveness verified.

Change control to penicillin blocks for API and FPP were checked, followed up and CAPA verified following from the last inspection. The CC was still ongoing and had not been closed at the time of inspection.

Deviation control

The SMP for Deviation controls was briefly discussed. The deviation reported for the period between 1 April – June 2023 was documented. The investigation of a deviation related to the autoclave located in the quality control laboratory was reviewed and discussed.

OOS investigation

The SMP for OOS investigations was briefly discussed. The OOS reported for the period between 1 April – June 2023 was documented. The investigation of OOS and the CAPA executed were checked.

CAPA's and investigation

The SMP for CAPA investigations was briefly discussed. The CAPAs raised for the period between 1 Jan – March 2023 was checked.

Quality Risk Management

The SMP for QRM investigations was discussed. Risk Priority Number was determined based on Probability (P), Occurrence (O) and Severity (S). The risk associated with the manufacturing of product in a multipurpose product manufacturing site taking in account HBEL was checked. HBEL

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risk for all current products were conducted and completed. Information as per Risk Register for OSD1 was noted.

Product Quality Review (PQR):
The PQR procedure was in place which described the process for the review of product performance and consistency of the manufacturing process. Various elements of the quality system and products were reviewed every 12 months as per the procedure. Process capability was calculated whereas CpK more than 1.3 was considered robust, CpK less than 1.3 required investigation.

2. Good manufacturing practices for pharmaceutical products

Generally Good manufacturing practices were implemented. The necessary human and physical resources with adequate premises, equipment and utilities were provided in support of the current FPP operational activities. Manufacturing processes were generally adequately defined. The manufacturing processes followed procedures as defined and documented in the BMRs and BPRs. The personnel were appropriately qualified and adequate training was conducted.

3. Sanitation and hygiene

Premises and equipment in the FPP production area were maintained at a satisfactory level of cleanliness at the time of inspection. Personal hygiene and sanitation appeared satisfactory. Areas were cleaned frequently in accordance with an approved written programme. Personnel at the site were seen to be performing their duties in an organized and diligent manner.

The facilities and procedures for sanitation and hygiene established on site were found to be adequate and supported by relevant SOP's. Sanitation of clean areas was performed frequently in accordance with a SOP. The SOP for Cleaning, and disinfectants identified the 4 Clean class area (Class A/B, C, D) layout and disinfectant to be used per each clean class. Effectiveness of disinfectants was checked in accordance with the Environmental Programme. The disinfectant interchangeable programme for Class D was reviewed.

4. Qualification and validation

A Validation Master Plan (VMP) was in place describing the principles of validation. In general, production and laboratory equipment had to be qualified/calibrated prior to use and after any significant change.

Process validation
Process validation was performed according to the documented procedure.

Validation of analytical methods
The SOP for analytical method validation was available and reviewed.

Cleaning validation
The SOP for cleaning validation and validation plan were reviewed. The cleaning matrix for the products manufactured in OSD I Workshop were discussed. The cleaning validation protocol of specific products were reviewed and found accepted.

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Computerized system validation

Computerized systems and PLC with new interfaces were installed on several pieces of existing equipment.

The manufacturer had a policy and documented procedures that addressed data integrity. The list of all critical IT systems, usage and validation status was available. Company electronic data was supported by the SOP on data disaster recovery, data backup and retrieval. Validation of the laboratory instruments and software was performed.

5. Complaints

A management policy for handling of customer complaints was established. No market complaints were received between January – 10 September 2023.

6. Product recalls

Product recall followed the principles described in the management policy. The depth of Recalls was categorized into three levels depending on criticality with specified timeline for completion. No recalls were conducted between January – 10 September 2023. The SOP provided appropriate instructions to recall/remove products from the market.

7. Contract production, analysis and other activities

Guilin acts as Contract Acceptor to manufacture for *Shanghai Fosun Pharmaceuticals* for application number *CV023, Molnupiravir capsules 200mg.*

In addition, Guilin acts as Contract Giver for the manufacturing of various products which includes inter alia Chinese Traditional Medicines and Penicillin containing products. High level Contracts were available.

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

The SMP for Self-Inspection required a yearly inspection plan covering all areas of the facility. A self-inspection check list was available. The self-inspection team was led by QA. An audit plan for site inspections 2023-1 was checked.

9. Personnel

The responsibilities of staff and their specific duties were recorded in written job descriptions. Personnel interviewed during the inspection were aware of the principles of GMP. Organization charts and job descriptions were available. Job descriptions of QA Manager, QA Assistant Manager and QP were reviewed and discussed.

10. Training

Training was managed according to the SMP. Training was divided into induction training, cGMP, on the job training and external training. Training was evaluated through questionnaires and a passing grade were set. Assessment records following training were available. For purposes of Laboratory training, SOP on qualification verification and laboratory staff competence was checked. Training received by staff members were verified and found acceptable.

11. Personal hygiene

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Changing and washing before entry to production areas followed written procedures. Direct contact was avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk products. The level of hygiene observed, and the measures taken to maintain hygiene requirement were found to be satisfactory.

The SMP addressed company policy on occupational health checks and physical examinations. Contracts with a local hospital for required health checks including eye tests were available.

12. Premises

Documented layouts of the facilities were available. Generally, the premises were located, designed, constructed, and maintained to suit the operations to be carried out. Production premise OSD-I was designed to allow production in a unidirectional flow supported by the requisite cleanliness levels with the core process areas designed to maintain the cleanliness level at Grade D condition.

All storage areas were designed to maintain a controlled environmental condition as per the requirement (Raw material, Primary packaging material, Secondary Packaging Hall, Finished Goods Store).

Penicillin API, OSD and injections were previously manufactured on site in three dedicated blocks. Penicillin production ceased with manufacturing being contracted out and the Penicillin manufacturing block decontaminated. The area was being recommissioned for purposes of manufacturing for the domestic market, storage of spare parts and archiving of documentation. During the inspection it was observed that commissioning of PEN-I API was still ongoing.

Warehouses

The facility had three warehouses applicable to the OSD manufacturing:

- Automated warehouse (storage of excipients, APIs) with temperature-controlled areas according to product storage requirements
- Label warehouse for printed labels (labels with product name and code), and
- Packaging warehouse for packaging materials (primary and secondary packaging). All warehouses applicable to OSD manufacturing were visited.

QC laboratories

Chemical/instrumental laboratory was located in a separate building. The laboratory had adequate space for the orderly placement of equipment and materials and to perform tests. Appropriate specifications were established. Access to laboratory premises was restricted to authorized personnel.

Microbiological laboratory premises were separated from chemical laboratory and was located on the different floor of the laboratory building. The microbiological laboratory layout involved separate rooms/areas that provided for media preparation and sterilization, testing of sterility and endotoxin, microbial limit etc.

Water system

Feed water to the plant was of municipality grade. The water system consisted of one generation system for PW linked to several distribution systems which supplied PW and WFI to OSD, INJ I & II and Laundry. PW was produced by double RO system. WFI was produced by distillation. The SOP

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for PW system equipment in manufacturing centre for dosage form, SOP for WFI operation procedure and PW operation records were checked.

13. Equipment

Equipment installed in the production OSD-I was multi-purpose. In general, the equipment used in the manufacturing, processing, and packaging was of appropriate design and construction for the required processes. The equipment was placed in a suitable location to facilitate operations for use, cleaning, and maintenance. All production equipment reviewed was identified as to its content or purpose with appropriate status of cleanliness identified.

Equipment maintenance and cleaning

The equipment preventive maintenance was managed according to the documented SOP. The maintenance schedule for January to June 2023 was available for review. Equipment cleaning area in OSD-I was visited.

14. Materials

Incoming materials were purchased from approved suppliers, sampled, and tested according to specifications and testing procedures. Receipt, warehousing, and release of starting materials were managed with WMS (Warehouse Management System) as per SOP. Approved, signed and dated testing procedures and specifications were available for starting material, packaging materials and for finished products.

The status of materials staged in the production area was spot checked and discussed. The procedure and operation for handling of rejected material were checked and discussed.

15. Documentation

In general, documentation was designed, prepared, reviewed, and distributed according to a documented procedure. Quality system documents were regularly reviewed and kept up to date. The procedure on allocation of a batch number and a list of all product codes were checked and discussed. The SMP on record management and issuance of BMR and BPR were checked.

During the inspection the Inspectors reviewed several BMRs of PQed products for process validation, production instruction, IPC, FPP release, CoA verification and EM etc.

16. Good practices in production

The manufacturing processes were performed and recorded according to instructions in the batch production records. Production of Amodiaquine (hydrochloride) dispersible tablets was in operation at the time of the inspection. Tablet manufacturing cubicles including material dispensing, granulation, compression, coating, primary and secondary packaging areas and bulk tablets storage rooms in OSD-I were visited. Manufacturing records of the products in production were checked and found acceptable.

In-process quality control tests were performed in dedicated IPC testing areas within the OSD-I production block. IPC testing procedures were checked. Primary packaging lines were visited. Since the last inspection new equipment for purposes of tablet inspections had been introduced. The SMP on reprocessing and reworking of FPP and API was reviewed.

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17. Good practices in quality control

The QC laboratories were separated from production areas. The laboratories have been designed and equipped with facilities for chemical, instrumental, microbiological and stability chambers. A new LIMS system was under development.

Sample receiving

Testing samples receiving and allocation to analysts are conducted formally and recorded as per the SMP. Logbooks for received API, raw materials, IPC samples and finished products were checked.

Laboratory equipment

Most of the laboratory equipment was linked with computerized software, with some standalone instruments such as UV, ICP, IR and AAS. Information was saved in real time on a separate laboratory server and the general server of the company. The SOP for the computerized system management was checked and discussed.

Calibration of laboratory equipment

Calibration of analytical weighting balance was assessed. Calibration of dissolution apparatus was verified. Mechanical and chemical calibration was performed. Equipment usage log and maintenance records were available. Calibration and system suitability tests for IR apparatus were verified.

Biowaiver dissolution studies: MA178

Comparative dissolution profile of biowaiver application for Pyrimethamine/Sulfadoxine Tablet 12.50mg/250mg was reviewed. The method validation SOP and CoA of the test and the reference for both batches were reviewed.

Microbiology laboratory equipment

Full set of data was available and was checked for calibration of balances, incubators, fridges, laminar air flow benches. Standard weights were externally calibrated according to the External calibration program.

Stability monitoring

Stability was performed followed the SOP with samples stored in a walk-in stability chamber. Temperature and humidity mapping was carried out periodically. Temperature and humidity were monitored electronically. Stability chambers were equipped with alarm systems. Stability was performed annually on one batch of product.

The stability study report for *Molnupiravir* CV023 capsules blister packed at the storage conditions of 40 ± 2°C / 75 % ± 5 % RH and 30 ± 2°C / 75 % ± 5 % RH were checked.

Reference material

Working reference standards were prepared in house with expiry date indicated. Usage of reference materials were recorded. Expiry date for pharmacopeial reference standards were checked online. The log recording expiry dates of chemicals and reference standards were checked and discussed.

Retention samples

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Retention samples were kept in the same packaging for commercial use. Samples were visually inspected every year.

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, ***Guilin Pharmaceutical Co Ltd***, located at ***No 43 Qilidian Road, Guilin, Guangxi, 541 004, 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-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://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1010-annex8-who-gmp-heating-ventilation-airconditioning.pdf?sfvrsn=c77698e2_0

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

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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
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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

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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***
TRS 1033 - Annex 4: WHO Guideline on data integrity

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
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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