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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Guilin Pharmaceutical Co Ltd**
Corporate address of manufacturer	Corporate: 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. No 43 Qilidian Road, Guilin, Guangxi, 541 004, China North latitude: N25º14'42.31", East longitude: E110 º 20'22.58"
Unit / block / workshop number	OSD workshop I Tablets (for WHO PQ program and other products for different markets)
Inspection details	
Dates of inspection	29-30 September & 01, 04-05 October 2021
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Guilin Pharmaceutical Co., Ltd is engaged in the manufacturing of various types of products 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 as follows: 1. OSD workshop I Tablets (for WHO PQ program and other products for different markets) 2. OSD workshop II Lactasin Tablets (Dedicated) 3. OSD workshop III Soft Capsules (Vitamin E Soft Capsules)
General information about the company and site	Guilin Pharmaceutical Co., Ltd is a member enterprise of Shanghai Fosun Pharmaceutical (Group) Co., Ltd since 2003. From the site master file, the manufacturer is engaged in the following manufacturing activities:

	<table><tr><th>Name of manufacturing center</th><th>Workshop name</th><th>Production line</th><th>Abbreviation</th></tr><tr><td rowspan="2">API manufacturing center</td><td rowspan="2">Multi-purpose workshop</td><td>Production line of artemisinin-derived APIs</td><td>API- I</td></tr><tr><td>Multi-purpose production line</td><td>API- II</td></tr><tr><td></td><td>Levamisole hydrochloride workshop</td><td>Levamisole hydrochloride production line</td><td>API- III</td></tr><tr><td rowspan="3">OSD manufacturing center</td><td>OSD- I workshop</td><td>General production line for dosage forms/ preparations</td><td>OSD- I</td></tr><tr><td>OSD- II workshop</td><td>Lactasin production line</td><td>OSD- II</td></tr><tr><td>OSD- III workshop</td><td>Soft capsules production line</td><td>OSD- III</td></tr><tr><td rowspan="4">INJ manufacturing center</td><td>INJ- I workshop</td><td>Production line for Artesunate for injection</td><td>INJ- I</td></tr><tr><td>INJ- II workshop</td><td>SVP production line (New)</td><td>INJ- II</td></tr><tr><td>INJ- VI workshop</td><td>SVP production line (Old, named as Workshop 7)</td><td>INJ- VI</td></tr><tr><td rowspan="2">INJ packaging workshop</td><td>Co-package center for Artesunate for injection (named as Workshop 8 and INJ-V formerly)</td><td>INJ-PA1</td></tr><tr><td>INJ-VI packaging line</td><td>INJ-PA2</td></tr></table>
History	The OSD workshop-I was last inspected by WHO PQ in October 2018. In addition, the site was inspected by Guangxi Medical Products Administration in April and September 2020 and August 2021 covering the OSD-I workshop.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Document Review included but not limited to: - Documentation system - Semi-finished & finished product testing and release - Job descriptions - Self-inspection - Change control - Annual product quality review - Deviation control - OOS, OOT, and investigation - Process validation - Cleaning validation - Quality risk management - Batch manufacturing records - Specifications and method of analysis - Computer system validation - Stability studies - Validation master plan - Electronic data and audit trail **Site areas visited:** - Manufacturing area covering granulation, compression, packing - Purified water system
Restrictions	The inspection was restricted to the production of the products listed in the inspection scope.
Out of scope	All other products were outside of the inspection scope.
WHO products covered by the inspection	1. **MA044** Artesunate Tablet 50mg 2. **MA045** Amodiaquine (hydrochloride) Tablet, Film-coated 150mg 3. **MA046** Amodiaquine (hydrochloride) + Artesunate Amodiaquine (Hydrochloride) Tablet + Artesunate Tablet 150mg + 50mg 4. **MA066** Pyrimethamine/Sulfadoxine + Artesunate

	Pyrimethamine/Sulfadoxine Tablet + Artesunate Tablet 25mg/500mg + 50mg 5. **MA068** Pyrimethamine/Sulfadoxine + Artesunate Tablets + Tablets 25mg/500mg + 100mg 6. **MA083** Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg 7. **MA084** Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg 8. **MA085** Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg 9. **MA098** Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Pyrimethamine/Sulfadoxine Tablets + Amodiaquine (hydrochloride) Film coated Tablets 25mg/500mg + 150mg 10. **MA113** Pyrimethamine/Sulfadoxine Tablet 25mg/500mg 11. **MA116** Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) dispersible tablets 12.5mg/250mg + 76.5mg 12. **MA117** Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) dispersible tablets 25mg/500mg + 153mg 13. **MA131** Dihydroartemisinin/Piperaquine (phosphate) Tablet, Film-coated 40mg/320mg 14. **MA139** Dihydroartemisinin/Piperaquine (phosphate) Tablet, Dispersible 40mg/320mg 15. **MA140** Dihydroartemisinin/Piperaquine (phosphate) Tablet, Film-coated 80mg/640mg 16. **MA141** Dihydroartemisinin/Piperaquine (phosphate) Tablet, Dispersible 20mg/160mg 17. **MA151** Dihydroartemisinin/Piperaquine (phosphate) Tablet, Film-coated 60mg/480mg 18. **MA153** Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg 19. **MA154** Artemether/Lumefantrine Tablet, Dispersible 40mg/240mg 20. **MA155** Artemether/Lumefantrine Tablet, Dispersible 60mg/360mg 21. **MA157** Dihydroartemisinin/Piperaquine (phosphate) Tablet, Dispersible 30mg/240mg 22. **MA164** Artemether/Lumefantrine Tablet 20mg/120mg 23. **MA165** Artemether/Lumefantrine Tablet 80mg/480mg
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**

1. Pharmaceutical quality system

The company has established a quality management system based on the requirement of national and international regulatory authorities. The quality and production departments operate independently under different leadership. Senior management demonstrated a commitment to the QMS by granting adequate resources to implement, support and manage the QMS. Senior management also participates in the system through the conduct of periodic management review meetings, discussion of PQR`s and the PQS itself. The quality management system was divided into two parts, i.e. quality assurance and quality control. The Vice President (Head of Quality) was overall responsible for the management of product quality.

Product Quality Review (PQR)

The PQRs were performed following the Standard Management Procedure (SMP) for annual product quality review (APQR).

According to the SOP PQR shall be conducted annually on rolling basis. The PQR included review of critical process parameters, in-process controls, critical quality attributes for bulk tablets. Trend and graphical analysis of the IPCs, CPPs, CQAs were performed.

Batch release

A system of batch release was in place and SMP for Product release was in place.

Change control

The SMP for change control was discussed. The procedure stated that a change related to research work of new products in the trial production stage of the GMP production workshop was not handled through this change control procedure instead through a separate procedure. Rest of the changes were handled through this procedure.

Issues noted from this section have been addressed and will be verified during future inspections.

2. Good manufacturing practices for pharmaceutical products

Basic principles of good manufacturing practices were described and implemented. Manufacturing processes were generally adequately defined and documented in BMRs and BPRs. Required resources were available, including adequate premises, equipment, and utilities. Appropriately qualified personnel were employed.

Issues noted from this section have been addressed and will be verified during future inspections.

3. Sanitation and hygiene

Premises and equipment were generally cleaned according to established procedures. Change rooms were well maintained and authorized instructions displayed the steps and dress code.

4. Qualification and validation

The qualification and validation programs were designed to evaluate the manufacturing process and process equipment to assure quality and cGMP compliance. Qualification programs of area and equipment's were performed periodically to ensure the suitability of the area and equipment. Validation programs were established to verify and document the ability to attain reproducible results during manufacturing, packaging, testing and cleaning operations.

Cleaning validation and process validation were reviewed.

Issues noted from this section have been addressed and will be verified during future inspections.

5. Complaints

Complaints were managed according to the procedure. Several complaints related to WHO PQed products were received and reviewed as per this procedure.

Issues noted from this section have been addressed and will be verified during future inspections.

6. Product recalls

The product recall was managed according to the procedure. Recalls were classified into three levels with specified time requirements. The recall of ASAQ tablets due to an OOS on impurity D was discussed. The recall was trigged by complaint. The company submitted a dossier variation and revised specification for impurity D to demonstrate that the affected batches are meeting the specification.

Issues noted from this section have been addressed and will be verified during future inspections.

7. Contract production, analysis and other activities

No external contracts were applicable for production and routine testing operations relating to the inspection scope.

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

Self-inspections (internal audits) were performed annually according to standard procedure. A self-inspection report 2020 for an internal audit to injection production was reviewed. Further improvement to allow for the application of a risk-based self-inspection process was discussed.

Suppliers were required to be qualified before materials were sourced and a list of qualified suppliers was available.

Issues noted from this section have been addressed and will be verified during future inspections.

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 in general. Organization charts and job descriptions were available.

Issues noted from this section have been addressed and will be verified during future inspections.

10. Training

GMP training was managed according to the procedure. The training of a QA staff responsible was reviewed.

Issues noted from this section have been addressed and will be verified during future inspections.

11. Personal hygiene

Personnel gowning procedure was appropriate and was generally followed. Personnel was medically examined before being offered a contract and then annually.

Issues noted from this section have been addressed and will be verified during future inspections.

12. Premises

All core process areas were designed to maintain the cleanliness level as per ISO Class 8 (Class 100,000) at rest condition (Sampling, Dispensing, Granulation, Compression, Coating, and Primary Packing area). Sampling and Dispensing areas were provided with a weighing booth for API sampling and Dispensing and Reverse Laminar airflow workstations (RLAF) for containment of dust. All storage area is designed to maintain a controlled environment condition as per the requirement (Raw material, Primary packaging material, Secondary Packaging Hall, Finished Goods Store). Surrounding corridors and passages are ISO 8 (Class 100,000) at rest condition and maintained at positive air pressure gradient in relation to all processing areas.

Building 5 has two floors covering the OSD manufacturing center (OSD-I, OSD-II, OSD-III) and INJ manufacturing center (INJ-I, INJ-II).

The QC laboratory was located in building 4 having an area of 3427 m2. It was divided into five floors as follows:

- F1: QC Administration, stability Study
- F2: Physical and Chemical Testing and Instrumental Testing
- F3: Microbiological Lab, Sample retention
- F4 & F5: R&D Department

The QC laboratories were separated from production areas. The laboratories have been designed and equipped with facilities for chemical, instrumental, microbiological and stability testing.

The storage areas were of sufficient capacity to allow orderly storage of various categories of materials such as starting and packaging materials, finished products, products in quarantine, released products, rejected and returned products. Receiving and dispatch bays were separated and protected materials and products from the weather. A printed packaging material was stored in accessed control areas.

The water system located in the OSD building was inspected. It included one generation system for PW linked to 5 distribution systems supplied PW and WFI to OSD, INJ I & II and Landry. WFI was produced by distillation. The following documents were reviewed during the inspection.

- SOP for PW system equipment in manufacturing centre for dosage form,
- SOP for WFI operation procedure
- PW operation records were reviewed

Issues noted from this section have been addressed and will be verified during future inspections.

13. Equipment

The equipment used in the manufacturing, processing, and packaging was of appropriate design, adequate size, and complied with cGMP norms. The equipment was placed in a suitable location to facilitate operations for their use, cleaning, and maintenance. Validation of the laboratory instruments and software was performed.

Issues noted from this section have been addressed and will be verified during future inspections.

14. Materials

The warehouse was briefly visited. Incoming materials (active, excipients, packaging materials) were received through the receiving bay. The receiving bay was equipped with a trap station used for rodent bait. The weakness of material code management in SAP and the manual system reviewed showed that a comprehensive CAPA needs to be implemented following the observation made in the last inspection.

Product return management procedure was available and reviewed.

Issues noted from this section have been addressed and will be verified during future inspections.

15. Documentation

Site documentation was controlled by the Quality Assurance Department. The users of the individual departments prepare procedures (SOPs) in standard format as per the SOP for SOP Writing. Site documentation control system procedure was in place describing the preparation, checking, authorization, controlling of documents and distribution. Quality Assurance was responsible for controlling and distributing documents. Master documents were stored in the Documentation room having access control and lock and key.

Issues noted from this section have been addressed and will be verified during future inspections.

16. Good practices in production

Production operations followed defined procedures. Significant deviations from the initial protocol were recorded and investigated, root causes were determined and CAPAs were implemented where necessary. Checks on yields and reconciliation of quantities were carried out. Access to production premises was restricted to authorized personnel. Production rooms appeared to be well maintained and clean. Stainless steel bins and containers were used for production and storage of in process products. Metal detectors were challenged before, during and after the batch and in event of re-commissioning. Punches/dies rotation was ensured, dimensions checks were performed.

The packaging area had several packing lines and most of them China made. Most of the packing lines were semi-automatic except few were fully automatic line for bilayered tablets.

Issues noted from this section have been addressed and will be verified during future inspections.

17. Good practices in quality control

The site has its quality control laboratory (QCL) comprising of different sections such as Raw Material Analysis, Packaging Material Analysis, In-process, Finished Product Analysis, Microbiology, and Stability testing. The QCL was equipped with a number of technical and support staff in each section. The laboratory was equipped with commonly used and sophisticated analytical testing instruments and equipment. The inspectors visited the quality control laboratory for the verification of chromatographic results related to recent complaint received for Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) dispersible tablets. In general, the analysis was performed following the standard management procedure.

Issues noted from this section have been addressed and will be verified during future 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, ***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 WHO Guidelines referenced in the inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

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 GMP for APIs*** or ***TRS No. 957, Annex 2***
   http://www.who.int/medicines/publications/44threport/en/

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

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
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

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**
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

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
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

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 GPPQCL Guidelines or ***TRS No. 957, Annex 1***
   http://www.who.int/medicines/publications/44threport/en/

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 2
   Short name: WHO TRS No. 957, Annex 2
   http://www.who.int/medicines/publications/44threport/en/

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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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***
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
    http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

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
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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*** http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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*** http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3*** http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.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*** http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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*** http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5
Short name: WHO GDRMP or ***WHO TRS No. 996, Annex 5***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10
Short name: WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf