World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the FPP manufacturer

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer	Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd
Address	16, Lanqing Yilu, Hi-Tech Zone, Guanlan, Longhua New District, Shenzhen, China Post Code: 518110 North latitude: 22°34′13.48″N East longitude: 114°09′0.08″E
Corporate address of manufacturer	As above
Inspected site	
Address of inspected manufacturing site if different from that given above	As above
Unit / block / plant number	Powder for Injection workshop no 1, line III
Inspection details	
Dates of inspection	21 - 25 January 2019
Type of inspection	Routine
Introduction	
Brief summary of the manufacturing activities	The main activity is the manufacturing, packaging, labelling, testing and storage of: • Powders for injection • Tablets • Capsules • Granules • Dry suspensions
General information about the company and site	Sinopharm Zhijun (Shenzhen) Pharmaceutical Co. Ltd., subordinated to China National Pharmaceutical Group, was founded in 1985. Zhijun (Shenzhen) focusses on the manufacture of finished antibiotics and finished pharmaceuticals for respiratory system.

History	The previous inspection by WHO PQT was performed in October 2016. The site has been inspected by the following authorities:

Authority	Dates of inspection
Guangdong Province FDA	2013 December
AEMPS Spain	2013 June
MPA Sweden	2014 January
WHO	2015 October
CFDA	2016 February
AEMPS Spain	2016 May
GDFDA	2016 September
German authority	2016 November
Guangdong Province FDA	2017 May

Brief report of inspection activities undertaken	
Scope and limitations	
Areas inspected	See Part 2 below
Restrictions	N/A
Out of scope	Products out of scope of WHO PQ
WHO product numbers covered by the inspection	Powder for Solution for Injection

Abbreviations

ADE	acceptable daily exposure
ADR	adverse drug reaction
AHU	air handling unit
ALCOA	attributable, legible, contemporaneous, original and accurate
API	active pharmaceutical ingredient
APQR	annual product quality review
AQL	acceptance quality limit
BDL	below detection limit
BET	bacterial endotoxin test
BI	biological indicator
BMR	batch manufacturing record
BPR	batch packaging record
CAPA	corrective actions and preventive actions
CC	change control
CCEA	complete, consistent, enduring, available
CFU	colony-forming unit
CMCC	Chinese Medical Bacteria Strain Collection

CoA	certificate of analysis
CoC	certificate of compliance
Cpk	process capability index
DQ	design qualification
EM	environmental monitoring
EU	endotoxin unit
FAT	factory acceptance test
FG	finished goods
FMEA	failure modes and effects analysis
FPP	finished pharmaceutical product
FTA	fault tree analysis
FTIR	Fourier transform infrared spectrometer
GC	gas chromatograph
GMP	good manufacturing practice
HACCP	hazard analysis and critical control points
HPLC	high-performance liquid chromatograph
HVAC	heating, ventilation and air conditioning
ID	identity
IR	infrared spectrophotometer
IPC	in process control
IQ	installation qualification
KF	Karl Fisher
LAF	laminar air flow
LIMS	laboratory information management system
LoD	limit of detection
LOD	loss on drying
M	meter
MA	marketing authorization
MB	microbiology
MBL	microbiology laboratory
MF	master formulae
MHRA	Medicines and Healthcare Products Regulatory Agency
MR	management review
NIR	near-infrared spectroscopy
NMR	nuclear magnetic resonance spectroscopy
NRA	national regulatory agency
OOS	out of specification
OOT	out of trend
OQ	operational qualification
PAO	poly alpha olefin
Ph. Eur	European Pharmacopoeia
PHA	preliminary hazard analysis
PD	pressure differential

PM	preventive maintenance
Ppk	process performance index
PQ	performance qualification
PQR	product quality review
PQS	pharmaceutical quality system
PRC	product release certificate
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 system
RCA	root cause analysis
RH	relative humidity
RM	raw materials
RS	reference standard
SAP	system applications products for data processing
SFG	semi-finished goods
SMS	short message service
SOP	standard operating procedure
STP	standard test procedure
T	temperature
TAMC	total aerobic microbial count
TFC	total fungal count
TLC	thin layer chromatography
TMC	total microbial count
TOC	total organic carbon
TSB	tryptic soy broth
UPS	uninterruptible power supply
URS	user requirements specifications
USP	United States Pharmacopeia
UV	ultraviolet-visible spectrophotometer
VHP	vaporized hydrogen peroxide
VMP	Validation Master Plan
WFI	water for injections
WHO	World Health Organization
WS	working standard

Part 2	Brief summary of the findings and comments

1. Pharmaceutical quality system (PQS)

Principle

Production and control operations were specified in written form and GMP requirements were essentially being met. Managerial responsibilities were specified in written job-descriptions. Product and processes were monitored, and the results considered during batch release; regular monitoring and reviews of the quality of pharmaceutical products were being conducted according to documented schedules and procedures.

Data integrity

The following SOPs were briefly discussed:

- "Data Integrity Management Procedure". Procedures explained ALCOA and CCEA approach.
- "SOP for QC Lab Electronic Data". The SOP explained the procedure of save, usage, audit trail, back-up, archival, restoration, rotation, storage and archival of QC lab electronic data.
- "Operation Procedure for Waters Chromatography Data System". Five privileges and access levels were specified.

Management review (MR)

SOPs "Quality Management Review System", "Management Procedure for Annual Quality Management System Review", "Quality Manual Annex" and "Annual Quality Goals 2019" were briefly discussed.

According to the SOP, MR should be performed every 6 months and the quality system should be reviewed annually. MR report was briefly discussed. Standard agenda specified in the SOP was followed.

Quality Risk Management (QRM)

SOPs "Quality Risk Management Procedure" and "Risk Assessment Report for Aseptic Filling on Powder for Injection Production Line" were briefly discussed.

Product Quality Review (PQR)

SOP "Annual Product Quality Review Procedure" was briefly discussed. Cpk was calculated using Minitab software.

At the time of the inspection, the PQR for all customers for 2018 was under preparation. Hence, PQR for XX Injection was briefly discussed.

Deviations/incidents and CAPA management

SOP "Deviation Management Procedure" was briefly discussed. Deviations were classified as:

- Critical
- Major
- Minor

There was no specific CAPA procedure. The requirements were specified in SOP "Deviation Management Procedure". QA was responsible for the execution of the CAPAs.

A number of deviations and CAPAs were briefly discussed.

Change control (CC)
SOP "Management of Change Control" and its flow chart and register for 2018 were briefly discussed.
Changes were classified as:
- Critical
- Major
- Minor

If required, risk assessment should be performed in accordance to the SOP "Quality Risk Management". A number of major CCs were briefly discussed.

Complaints
SOP "Product Complaints Management", its flow chart and registers for 2017 and 2018 were briefly discussed.
Complaints were classified as:
- Quality complaints
- Medical Complaints
- Information consultation
- Counterfeit complaints

And

- Critical
- Major
- Minor

Trending of complaints was carried out annually.

Product recalls
SOP "Management of Product Recall" was briefly discussed. According to the procedure in the event there is no actual recall, a mock recall should be initiated annually. Recalls were classified as:
- Class I: Notification should be sent out within 24 hours.
- Class II: Notification should be sent out within 48 hours.
- Class III: Notification should be sent out within 72 hours.

Product returns
SOP "Management System for Returned Products" and returned products registers for 2017 and 2018 were briefly discussed.

Personnel

Visual inspector's qualification

SOPs "Training Management for Powder for Injection Production Workshop 1" and "Procedure for Visual Inspection Line" were briefly discussed. Visual inspector assessment was carried out:

- Monthly
- Quarterly

During the production process, visual inspectors had a break every 20 minutes. The list of qualified visual inspectors was presented to the inspectors. Theoretical training effectiveness was assessed by using open questions and multiple-choice questions.

2. Documentation system

Documents related to the manufacture of intermediates and APIs were prepared, reviewed, approved and distributed according to written procedures. The SOPs were also displayed at appropriate points. The issuance, revision, superseding and withdrawal of documents were controlled with maintenance of revision histories.

Documentation system was generally established. Documentation was a 4-level system.

The following SOPs were briefly discussed:

- "Numbering Procedure for International Cooperation Products Batch Number, Manufacturing Date and Expiry Date".
- "Issuing and Return of Materials - Product for Export".
- "Management of Reception Freshness, Retest Period, Storage and Expiry Date for Materials".
- "Management Procedure for Release of Intermediate and Finished Product" and its flow chart
- "Review and Archival of Testing Batch Record". Reviews were carried out using check lists, separate for sequence audit record.

3. Production system

Production operations followed defined procedures. Access to production premises was restricted to authorized personnel.

During inspection inspectors visited production Workshop No. 1, filling line No. III. Production process of powders for injection was a continuous process starting from vial washing till labelling and packaging. Inspectors saw powder for injection batch No. XX production operations. Visual control was performed on-line by two operators. Filling was carried out in restricted access barrier system - RABS.

SOP "Procedure for using RABS Gloves of Powder for Injection Production Workshop 1" was briefly discussed.

Cleaning and disinfection

The following SOPs were used for cleaning:

- "Cleaning and Disinfection Procedure for Grade B Area
- "Cleaning and Disinfection Procedure for Grade C Area
- "Cleaning and Disinfection Procedure for Grade D Area
- "Disinfection and Sterilization Procedure of VHP"

Validation protocol for "Vaporized Hydrogen Peroxide Fumigation in Powder for Injection Production Line 3" was briefly discussed.

Disinfectants

Efficacy tests of the disinfectants were performed according to protocol XX which covered a total of 17 disinfectants which were tested after 3 days.

Environmental monitoring of clean area (EM)

SOP "Environmental Monitoring for Clean Area in Powder for Injection Plant (European Union)" and sampling locations map were briefly discussed.

Yields and reconciliation

Checks on yields and reconciliation of quantities were carried out. The detail (calculations and requirements) regarding yield and material reconciliation was specified in SOP "Process Instruction for Powder for Injection (For Export)".

4. Facilities and equipment system

Production premises were designed to avoid the unnecessary entry of supervisory or control personnel. In clean areas, exposed surfaces were smooth, impervious and unbroken and designed to permit the repeated application of cleaning agents and disinfectants.

Equipment were located, designed, constructed, adapted and maintained to suit the operations to be carried out.

QC laboratories were separated from production areas. QC laboratory premises were spacious and designed to suit the operations to be carried out in them. There were adequate and suitable storage space for samples, reference standards, solvents, reagents.

A short visit was made to the warehouse. Incoming materials and finished products were quarantined after receipt and processing, until released for use or distribution. Materials management was carried out manually. API, finished products and packaging materials warehouses (for export) were seen to be maintained in good order. Sampling of primary packaging materials was carried out in separate room under Grade D environment. Separate AHUs were provided to maintain required storage T.

Qualification and validation
Qualifications and validations were performed according to prepared protocols. Significant deviations from the initial protocol were recorded and investigated, root causes were determined and CAPAs were implemented where necessary. Equipment qualifications were performed annually, and media fill validations were performed every 6 months.

Autoclave validation
Autoclave re-validation was performed annually for all loads. Three vacuum cycles were applied for porous loads sterilization. Pure steam was tested for superheat, dryness value and no-condensable.

Sterilization tunnel validation
Re-qualification of the sterilization tunnel was carried out annually. Endotoxins (3 log reduction) were spiked also in 12 vials. HEPA filter integrity tests were carried out using Poly Alpha Olefin (PAO) every 6 months.

Media incubation walk-in rooms qualification
For media fills: walk-in rooms were used. Walk-in rooms were qualified for 22.5 °C ± 2.5 °C and 32.5 °C ± 2.5 °C. Qualification was performed annually for all rooms and both temperatures.

Garment sterilization cycles validation
Qualification summary report for cleanroom garment laundry, drying sterilization was briefly discussed.

Utilities
PW
SOPs "Monitoring Procedure for Purified Water", "Monitoring Procedure for Water for Injection" and PW/WFI trends for 2017 and 2018 were briefly discussed.

Alert and action limits were specified. PW was used in the laundry of garments and first wash cycle for stoppers.

WFI
Samples from return loop for microbiological limit and endotoxin tests were collected and analyzed daily. Chemical test collected and analyzed weekly. Samples from other sampling points for microbiological limit and endotoxin tests were collected and analyzed weekly, for chemical test once in a month. Alert and action limits were specified.

Pure steam
SOP "Monitoring Procedure for Pure Steam" was briefly discussed. Samples from steam generation point for microbiological limit were analyzed daily, chemical test collected and analyzed weekly. Microbial testing from other sampling points weekly and chemical tests monthly.

Alert and action limits were specified for microbial limit. Trends for 2018 4th quarter were briefly discussed.

Compressed air
SOP "Compressed Air Monitoring Procedure" and trends for 2018 4th quarter were briefly discussed. Compressed air was used for delivering powder for injection to the vials.

Nitrogen gas
Nitrogen used in contact with product was purchase in cylinders.
SOP "Nitrogen, Carbon Dioxide Monitoring Procedure" and in-house specification for "Nitrogen in Cylinder for Medical Use" and 2018 4th quarter were briefly discussed.

5. Laboratory control system

The QC function consisted of QC Analytical and QC Microbiology departments.

Sampling of packaging materials
SOP "Packaging Materials Sampling" was briefly discussed. AQL was used.

Sampling of API
"Management Procedure for Sterile APIs (WHO)" was briefly discussed.

Analytical balances
Balances were verified daily and bi-annually according to the USP chapter 41 and 1251.

Reference standards
Reference standards were stored in locked refrigerators, T was recorded on-line every 20 minutes and checked once per week. Working standards were standardized against pharmacopoeia standards. Working standards were collected from the filling line and stored in the same packaging as finished product. Expiry date assigned was 1 year from the date of standardization. Text alarm system was connected to WI-FI which generated text message to responsible persons.

Retention samples
SOP "Retention Samples and On-Going Stability Studies" was briefly discussed. FPPs samples were retrained for 1 year after shelf life, APIs samples were retained for at least two years after release of product or at least one year after the shelf life of the finished product. Retention samples were checked visually annually. Retention samples were stored in mobile racks, storage was seen to be in good order.

Out of specification and out of trends (OOS & OOT)
SOP "Out of Specification and Out of Trend Investigation" also covered the handling of incidents. The SOP was based on the MHRA guideline for "Out of Specification and Out of Trend Investigations". The SOP was applicable to instrumental/chemical and microbiological laboratories OOS/OOTs and to starting materials, in-process controls, FPPs and packaging materials.

The register for 2018 was briefly discussed.

A number of OOS investigation records were briefly discussed.

Inspectors requested company to export to Excel sheets system and project audit trials for one commercial product. However, inspectors were not able to review in detail presented audit trials, because inspectors' laptops did not recognize Chinese language.

During inspection, Standard Test Procedure and analytical raw data was checked for powder for injetcion batch No XX. Analytical raw data was cross-checked with equipment log books, standard usage log books and column usage log books. No discrepancies were seen. All calculations were done manually.

HPLC
Injection sequence and approach to manual integration was specified in the "Operation Procedure for Waters Chromatography Data System".

QC Microbiology
There were several different laboratories:
- 3 laboratories for the aseptic sampling of starting materials (Grade A/Grade B background)
- 1 laboratory for sterility testing
- 1 laboratory for microbial limit testing (Grade A/Grade C background)
- 1 laboratory for the endotoxin testing (Grade D area)
- 1 laboratory for handling of positives (Class II Biological Safety Cabinet)
- 1 laboratory for microbial identification
- 1 laboratory for media preparation and incubation
- 1 laboratory for the sterilization of laboratory articles
- 1 laboratory for non-aseptic sampling (Grade D area)
- 1 laboratory with a separate autoclave for decontamination

6. Packaging and labelling system
During the inspection, packaging and labelling operations were seen for powder for injection batch No. XX. Labelling and packaging line were connected to the filling/capping line and was continuous operation. Roll labels were used. Line clearance procedure was in place. Labelling machine was equipped with labels reader and pharma code reader.

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, ***Sinopharm Shenzhen Zhijun Pharm,*** located at ***16, Lanqing Yilu, Hi-Tech Zone, Guanlan, Longhua New District, Shenzhen, 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. WHO guidance on 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 guidance on Stability testing or WHO TRS No 1010, Annex 10**
https://extranet.who.int/prequal/sites/default/files/documents/TRS1010_Annex10.pdf