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

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer	**Strides Shasun Limited**
Corporate address of manufacturer	'STRIDES HOUSE', Bilekahalli, Bannerghatta Road, Bangalore - 560 076. INDIA ☎ : 91-80-67840521 🖷 : 91-80-67840800
Inspected site	
Address of inspected manufacturing site if different from that given above	Strides Shasun Limited A1/B, SIPCOT Industrial Complex, Kudikadu Village, Cuddalore – 607 005, Tamil Nadu, India. INDIA ☎ : 91-4142-285400 🖷 : 91-4142-239709 GPS coordinates of the site: Latitude: North 11^0 41.104' Longitude: East 79^0 45.308' D-U-N-S Number 65-056-4045
Unit / block / workshop number	Production block 4
Manufacturing license number	License No.: 703 issued by Directorate of Drugs Control, India Scope of license: License to manufacture for sale of drugs for export and domestic sale.
Inspection details	
Dates of inspection	24-26 October 2016
Type of inspection	Follow-up inspection
Introduction	
Brief summary of the manufacturing activities	Manufacture including production, quality control and release of non-beta lactam and non-penicillin group: • Active Pharmaceutical Ingredients and intermediates
General information about the company and site	Shasun Pharmaceuticals Limited was established in the year 1976. The firm set up its plant at Cuddalore, Tamil Nadu, India in the year 1991 to manufacture Active Pharmaceuticals Ingredients and its intermediates. This Cuddalore API site is situated at A1/B, SIPCOT Industrial Complex, in Kudikadu village,

Cuddalore - 607005, which is about 180 km away from Chennai, the capital of Tamil Nadu state (India). This site is a multiproduct facility manufacturing APIs and its intermediates for different Regulatory markets. The site occupies an area of about of 66000 m^2. This API site was inspected by various Regulatory Authorities.

On November 19, 2015, pursuant to the strategic decision to combine the two companies Shasun Pharmaceuticals Limited was amalgamated and merged with Strides Arcolab Limited. The name of the new combined business is "Strides Shasun Limited".

Strides Shasun is having the following manufacturing facilities in India, Italy and Africa:

- Strides Shasun Limited API & FPP Puducherry, India
- Strides Shasun Limited R&D Centre in Chennai, India
- Strides Shasun Limited FPP in Bengaluru, India
- Strides Emerging Markets Private Limited FPP in Bengaluru, India
- Strides Shasun Limited FPP in Palghar, India
- Strides Vital Nig. Ltd FPP in Lagos, Nigeria
- Strides Pharmacare Factory for Human And Veterinary Medicines FPP in Khartoum, Sudan
- Strides Pharma Cameroon FPP in Douala, Cameroon
- Strides Pharma Mozambique Limited FPP in Maputo, Mozambique
- Beltapharm Spa FPP in Milano Italy
- API - R&D Centre in Chennai, India
- Two API manufacturing facilities in Puducherry and Cuddalore, India
- One Formulation facility in Puducherry, India
- One API facility at Dudley, UK, which is involved in CRAMS business

Inspected site has the following manufacturing blocks:

- Production blocks I – V
- Packaging sections I, II, III, V, VII, IX, X, XI, XII, XIII and XIV

History

The site was last inspected by WHO in April 2015. The site has also been inspected by the following regulatory authorities:

Date of inspection	Authority	Scope of inspection
14- 16 June, 1999	US FDA	GMP inspection
11-15 Nov 2002	US FDA	GMP inspection
2-3 Oct 2003	EDQM	GMP inspection
26-30 Mar 2007	US FDA	GMP inspection
16- 20 Oct 2008	Danish Medicines Agency,	GMP inspection
11-16 Oct 2010	US FDA	GMP inspection
19 – 21 March, 2012	WHO – Geneva	Prequalification Inspection
8 - 9 Nov, 2012	KFDA (MFDS) - Korea	GMP Inspection
29 Nov -1 Dec, 2012	WHO – Geneva	Pre-Qualification Inspection

	7 - 9 March, 2013	COFEPRIS - Mexico	GMP Inspection
	9 - 13 June, 2014	US FDA	GMP Inspection
	23 - 27 June, 2014	COFEPRIS - Mexico	GMP Inspection
	24 - 27 Nov, 2014	EDQM & EMA (HPRA -	EU GMP Inspection
	20 - 22 April, 2015	WHO – Geneva	Prequalification Inspection
	31 Aug – 4 Sep, 2015	COFEPRIS - Mexico	GMP Inspection
	17- 21 Apr 2017	US FDA	GMP Inspection
Brief report of inspection activities undertaken			
Scope and limitations			
Areas inspected	Pharmaceutical Quality System Production System Facilities and Equipment System Laboratory Control System Materials System		
Restrictions	N/A		
Out of scope	Packaging and Labeling System and microbiological laboratory		
WHO product numbers covered by the inspection	• APIMF 177 Cycloserine • APIMF 236 Tenofovir disoproxil (fumarate)		

Abbreviations		
	AHU	air handling unit
	ALCOA	attributable, legible, contemporaneous, original and accurate
	API	active pharmaceutical ingredient
	APQR	annual product quality review
	BDL	below detection limit
	BMR	batch manufacturing record
	BPR	batch packaging record
	CAPA	corrective actions and preventive actions
	CC	change control
	CFU	colony-forming unit
	CoA	certificate of analysis
	CpK	process capability index
	DQ	design qualification
	EM	environmental monitoring
	FAT	factory acceptance test
	FBD	fluid bed dryer
	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
MB	Microbiology
MBL	microbiology laboratory
MF	master formulae
MR	management review
NIR	near-infrared spectroscopy
NMR	nuclear magnetic resonance spectroscopy
NRA	national regulatory agency
OQ	operational qualification
PHA	preliminary hazard analysis
PM	preventive maintenance
PpK	process performance index
PQ	performance qualification
PQR	product quality review
PQS	pharmaceutical quality system
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
RH	relative humidity
RM	raw materials
RS	reference standard
SAP	system applications products for data processing
SFG	semi-finished goods
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

URS	user requirements specifications
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WS	working standard

Part 2	**Brief summary of the findings and comments (where applicable)**

Note: This WHOPIR is based on WHO inspection report (October 24-26, 2016) and desk review of EMA inspection report (January 9-11, 2017), CAPAs and other relevant documents review.

Brief summary of the findings and comments

1. Pharmaceutical quality system

In general the system for managing quality encompassed the organizational structure, procedures and processes. There were QA and QC departments that were independent of production. In general deviations from established procedures were documented and explained. Procedure was in place for notifying responsible management of regulatory inspections, serious GMP deficiencies, product defects and related actions.

Product Quality review

The SOP "Periodic product review" was discussed. PQR was conducted annually and should be reviewed and approved before end of March according to the company SOP.

PQR for Cycloserine API for 2015 was discussed. There was no reworked/reprocessed/returned batches, no OOS/OOT, no recall. There were two complaints.

Management review (MR)

The SOP "Quality System Review (QSR)" and log books "Quality system review & attendance 2016" and "Quality system review 2016" were discussed. QSR team was led by the Senior Vice President Quality. QSR team consisted of the heads of all departments. QSR was conducted monthly at unit level and at the corporate level. The following items were subjects of the QSR:

- Review of action plan as determined in the previous meeting, status of outstanding items/events
- Market complaints
- Deviations and change controls
- Validation summary
- PQR
- Audit summary
- Open CAPA from audits
- Technology transfer
- OOS/OOT
- QC analysis summary
- Material rejections
- Rejected batches

- Microbiology trends
- Training summary
- Recalls, returned goods, field alerts
- Concerns, recommendations and improvements

Quality risk management

The SOP "Quality risk management" and log book "Quality risk assessment" were discussed. The SOP was applicable for API sites and covered all quality system. FMEA was used as a tool.

Deviations

The SOP "Deviations" and flow chart were discussed.
Deviations were classified as:

- Critical
- Major
- Minor

Corrective actions and preventive actions (CAPA)

The SOP "Investigation and CAPA management" was discussed. There were no major deviations and only 1 critical deviation was logged in Trackwise.

Change control (CC)

The SOP "Change management" and CC log book for 2015 were discussed. The changes were initiated by the concerned departments. The substantial decisions during the investigation (in particular the implementation) were made by the QA department. There was no trending of changes and no discussion during MR meeting. The SOP was applicable for:

- Complaint management
- OOS/OOT
- Recalls
- Deviations
- Regulatory inspections
- Process performance trends and PQR
- QRM
- Improvement plans
- QS Review

Root cause investigation was part of the CAPA SOP, the following tools were specified:

- Applicable investigation checklist
- Cause effect diagram
- Brainstorming
- 5-whys

Complaints

The SOP "Complaints" was discussed. Complaints were classified as:

- Manufacturing (quality aspects of product both physical and chemical properties)
- Packaging (quality aspects of packaging)
- Quantity

Complaints log books were product wise as well as trending. According to the SOP trending should be performed quarterly.

Recall

The SOP "Product recall & market withdrawal" was discussed. There were no product recalls in recent years. According to the SOP a mock recall should be performed once in two years for domestic market and every three years for USA/Canada/rest of the world markets.
Recalls were classified as following:

- Class I – should be initiated within 24 hours
- Class II - should be initiated within 48 hours
- Class III - should be initiated within 5 days
- Class IV - should be initiated within 14 days

Supplier qualification

Supplier qualification and management was performed by corporate office.

Returns/rejects

Returned/rejected log books were product based.

Personnel

According to the company presentation, the site employed approximately 778 full time employees:

Manufacturing & Packaging	418
Quality Control	108
Quality Assurance	38
Warehouse	21
Engineering services	101
Administration & HR	16
Safety Environment & EHS	33
Others	43
Total	778

Personnel were wearing clothing suitable for the manufacturing activities.

2. Production system

Production block 4 was covered by the inspection. Block 4 was a multiproduct manufacturing facility. Cycloserine API was manufactured in block 4.

Tenofovir disoproxil manufacturing operations in block III were stopped in January 2014. Since that time Tenofovir disoproxil API was not manufactured. According to the planned changes Tenofovir disoproxil manufacturing will be moved to the Production Block 4.

Production operations took place on two floors.

Reactors, including glass lined reactors, were used for Cycloserine production. Centrifuge bags were dedicated for Cycloserine API. Bags were changed after two production batches.

Final processing step was carried out in “clean rooms” (ISO 8).

Production operations were recorded in the step wise BMRs.

3. Facilities and equipment system

In general buildings and facilities had adequate space for the orderly placement of equipment and materials. Mainly closed systems were used for production. Some manual operations were carried out, for example unloading materials from centrifuges.

There were defined areas for the:

- Receipt, identification, sampling, and quarantine of incoming materials, pending release or rejection,
- Quarantine before release or rejection of intermediates and APIs,
- Holding rejected materials before further disposition (e.g. return, reprocessing or destruction),
- Storage of released materials,
- Production operations,
- Laboratory operations.

Laboratory areas and operations were separated from production areas.

Ventilation, air and exhaust systems were provided for “clean rooms”. Permanently installed pipework was appropriately identified. PW was used in the manufacture of APIs and cleaning (final rinsing).

In general equipment used in the manufacture of intermediates and APIs were of appropriate design and adequate size, and suitably located for its intended use, production and permanently installed processing lines used during the production were appropriately identified. Equipment maintenance and calibration was done following written procedures.

VMP for Cuddalore site APIs and facility year 2016 was checked.

The SOP "Cleaning procedure – validation & Routine evaluation" was discussed. There were two types of cleaning used: batch to batch (type I) and product to product (type II).

The SOP "Cleaning of rotary cone vacuum drier cum blender during product change over", the SOP "Cleaning of centrifuge during product change over", the SOP "Cleaning of centrifuge" and SOP "Cleaning and checking of RCVD cum blender" were discussed.

The document "Protocol for the cleaning validation of Rebamipide stage-final" was presented to the inspectors. UV analytical method was used. MACO was based on 10 ppm criterion. It was noted that HPLC method was used for Rebamipide assay analysis.

The SOP "Procedure for swabbing" was discussed.

The SOP "Calibration of T indicators and controllers" was discussed. T indicators and controllers calibration was carried out on site. Calibration certificates for selected T indicators were presented to the inspectors.

The SOP "Particulate count test procedure", "Non-viable particulate count report" and HEPA filter integrity test report were discussed. AHU 1 layout and qualification was discussed. AHU consisted of the following filters cascade: G4→F8→F9→H13→H13. HEPA filters were installed in plenum and in the production rooms. Re-circulated air (10 – 15 %) was mixed with fresh air.

The procedure and records for the spark test of glass reactors and the SOP "Preventive maintenance of reactor" were discussed". Glass reactors spark tests were carried out every 2 years.

HVAC system serving block 4 "clean rooms" was inspected. Special attention was paid to the AHU No1.

PW system layout was discussed. PW system purification (installed in 2014) and storage tank and distribution system were installed in 2003 were discussed. Sanitization was carried out every week for 2 hours by hot water. Conductivity and pH were monitored on line, on-line TOC meter was under qualification. PQ storage tank had installed hydrophobic 0.2µm filter which was replaced every 3 months. UV lamp intensity and burning hours were specified and monitored. Chemical sanitization of RO membranes was carried out monthly.

VMP for computer system validation was discussed. Document explained validation policy, management of the master plan, validation approach, life cycle approach for computerized systems, and computerized systems retirement.

The SOP "Standalone systems backup tracking register", effective from 19 October, 2016 and previous SOP "Data back-up procedure" and back-up tracking register were discussed.

Computerized system inventory was presented to the inspectors.

CC record report and document “Impact assessment for XX system” No YY were discussed as well as system release notification for ZZ systems.

4. Laboratory control system

Documented procedures and standard test methods were available. Due to time limits laboratory inspection was limited and attention was paid only to the HPLC No XX and FTIR. FTIR was stand-alone instrument.

All HPLCs and GCs were connected to the Chromeleon software, version 7.2 SR4. There were 5 access levels to the HPLCs:

- Analyst
- Supervisor
- Manager
- Service engineer
- Administrator.

A QC lab signature specimen was presented to the inspectors. In-coming sample registers were product based.

The SOP “Management of Chromeleon 7.2 chromatographic data station” was discussed. It was said that manual integration was not allowed, however this was not reflected in the SOP.

Stability studies HPLC raw data were checked for Cycloserine API batch No XX.

The SOP “Bracketing of standards and general system suitability criteria during analysis was discussed.

5. Materials system

Written procedures describing the receipt, identification, quarantine, storage, handling, sampling, testing and approval or rejection of materials were available.

Suppliers of critical materials and packaging materials, selection, auditing and approval were carried out by corporate office. Lists of approved suppliers for Cycloserine were presented to the inspectors.

Materials management was carried out using SAP system and also paper based system. Upon receipt and before acceptance, containers of materials were examined visually, materials were held under quarantine until they have been sampled, tested and then released for use.

Solvents were store in underground tanks, for daily use solvents were stored in above ground tanks, close to the production blocks.

KSM, other substances and packaging materials were stored in one warehouse in different rooms. Primary packaging materials were stored in locked SS cabinets. Sampling and dispensing operations of solid RM, liquid RM and primary packaging materials were carried out in two

sampling/dispensing rooms located in the warehouse. Sampling and dispensing was carried out under the RLAF.

Containers from which samples were withdrawn were marked to indicate that a sample has been taken.

The SOP "Sampling" was discussed.

6. Packaging and labelling system

Cycloserine packaging and labelling operations of finished API was done in the same room as milling and sifting. During inspection packaging and labelling operations were not carried out. It was explained that computer generated, customer specific labels were printed in-house.

PART 3

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, a **Strides Shasun Limited** located at A1/B, SIPCOT Industrial Complex, Kudikadu Village, Cuddalore - 607005, Tamil Nadu, India was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for pharmaceutical products.

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 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
   http://www.who.int/medicines/publications/44threport/en/

2. 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
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six 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. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5
Short name: WHO TRS No. 961, Annex 5
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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 TRS No. 961, 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 prosecution 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. WHO good manufacturing practices for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3
Short name: WHO TRS No. 996, Annex 3
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf

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

23. 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

24. WHO good manufacturing practices for biological products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3
Short name: WHO TRS No. 996, Annex 3
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf