

**Prequalification Team Inspection services
WHO INSPECTION REPORT
API and FPP SITE**

Part 1	General information
Manufacturers details	
Company information	
Name of manufacturer	Ipca Laboratories Limited, Ratlam
Corporate address of manufacturer	125, Kandivli Industrial Estate, Kandivli (West), Mumbai - 400067 Maharashtra, India
Inspected site	
Address of inspected manufacturing site if different from that given above	P.O. Sejavta Dist. Ratlam – 457002 Madhya Pradesh, India GPS Coordinates: 23.334169N 75.037636E
Unit / block / workshop number	Building IBD- XII (Artesunate API) Building IBD – VIII 2 nd floor (sterile Artesunate API) Building Pharma – III (Artesunate powder for injection, Sodium Bicarbonate powder solvent for injection, Sodium Chloride powder solvent for injection)
Inspection details	
Dates of inspection	28 – 31 May 2018
Type of inspection	Follow-up
Introduction	
Brief summary of the manufacturing activities	IPCA Laboratories Ratlam was authorized to manufacture APIs, sterile APIs, Sterile liquids, Dry powders for injection, Oral solid dosage forms, Liquid oral dosage forms, Dry syrups and Ointments
General information about the company and site	Ipca Laboratories were established in 1949. The company has several formulation and API manufacturing sites in India as well as R&D centres. Their product portfolio includes over 150 formulations. Ipca's manufacturing facility at Sejavata, Ratlam is located 650 Km North-East of Mumbai and it was established in 1983. The site had several buildings where APIs and FPPs were manufactured. The following facilities were of interest to WHO prequalification: Building Pharma III (Aseptically prepared and terminally sterilized liquids and solids in ampoules and vials and Microbiological laboratory) Building IBD- XII (Artesunate API) Building IBD- VIII (Sterile Artesunate)

	Building IBD-II (Quality Control and Stability) Bulk Drug and raw/packaging materials warehouse Raw and Packaging Material Warehouse (FRM) Finished goods warehouse (FRM) Finished goods warehouse (APIs) Water Plant The Sterile Facility (Pharma - III) was inaugurated in 2011 and became operational in 2013. There were two independent manufacturing lines: • Dedicated aseptically filled powder line for Artesunate • Sterile Liquid filling (Ampoule) line. The following changes were being implemented in Building IBD VIII: Door replacement Autoclave Double Door New airlock entry Extension of garment wash area New AHU installed in non-controlled area Dynamic pass-box installation Grade D change room replacement of HEPA filters and air diffuser Other changes: Installation of automatic ampoule optical inspection machine in Pharma III Installation of software in the laboratory for incident and OOS management																											
History	This was the second WHO inspection of Buildings IBD-VIII and Pharma – III. The site was inspected by the following authorities in the last 3 years: <table><tr><th>Regulatory Approvals</th><th>Dosage form</th><th>Year</th></tr><tr><td>CDSCO - India</td><td>Sterile (Ampoule & Vial)</td><td>January, 2018</td></tr><tr><td>State Administration of Ukraine</td><td>OSD</td><td>November, 2017</td></tr><tr><td>Medicines Control Authority Zimbabwe [MCAZ]</td><td>OSD & Liquid Oral</td><td>May, 2017</td></tr><tr><td>NAFDAC- Nigeria</td><td>Sterile (Ampoule & Vial), OSD & Liquid Oral</td><td>March, 2017</td></tr><tr><td>GMP Certificate FDA - India</td><td>OSD & Liquid Oral</td><td>January, 2017</td></tr><tr><td>MOH - Belarus</td><td>OSD & Liquid Oral</td><td>January, 2017</td></tr><tr><td>National Drug Authority [NDA] - Uganda</td><td>Sterile (Ampoule & Vial), OSD & Liquid Oral</td><td>November, 2016</td></tr><tr><td>Ministry of health, Pharmacy board - Tanzania</td><td>Sterile (Ampoule & Vial), OSD & Liquid Oral</td><td>October, 2016</td></tr></table>	Regulatory Approvals	Dosage form	Year	CDSCO - India	Sterile (Ampoule & Vial)	January, 2018	State Administration of Ukraine	OSD	November, 2017	Medicines Control Authority Zimbabwe [MCAZ]	OSD & Liquid Oral	May, 2017	NAFDAC- Nigeria	Sterile (Ampoule & Vial), OSD & Liquid Oral	March, 2017	GMP Certificate FDA - India	OSD & Liquid Oral	January, 2017	MOH - Belarus	OSD & Liquid Oral	January, 2017	National Drug Authority [NDA] - Uganda	Sterile (Ampoule & Vial), OSD & Liquid Oral	November, 2016	Ministry of health, Pharmacy board - Tanzania	Sterile (Ampoule & Vial), OSD & Liquid Oral	October, 2016
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	INVIMA - Columbia	OSD	September, 2016	
	DIGEMID - Peru	OSD	April, 2016	
	Direction de la Pharmacies et du Medicament [DPM] - Ivory Coast	Sterile (Ampoule & Vial), OSD & Liquid Oral	March, 2015	
	FDA - Ghana	Sterile (Ampoule & Vial), OSD & Liquid Oral	June, 2015	
	GMP Certificate FDA - India	Sterile API	June, 2015	

Brief report of inspection activities undertaken - Scope and limitations

Areas inspected	This was a follow up inspection focusing on the areas where observations and relevant CAPA were implemented following the most recent WHO inspection in 2017. In addition, this inspection briefly covered Artesunate API manufacture in Building IBD – XII as well as areas that were not covered during the last inspection. More specifically warehouses, sampling, stability, PW + WFI systems, HVAC, computer system validation, depyrogenation tunnel and release of API and FPP
Restrictions	Due to time constraints the microbiological laboratory was not inspected. However, this was inspected during the previous WHO inspection in August 2017
Out of scope	Products and facilities not related to WHO Prequalification
WHO products covered by the inspection	Artesunate 60 mg powder for injection including Sodium Bicarbonate 5 % w/v and Sodium Chloride Powder 0.9 % w/v solution for injection.

Abbreviations	Meaning
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
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
IR	infrared spectrophotometer
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
NMR	nuclear magnetic resonance spectroscopy
NRA	national regulatory agency
OQ	operational qualification
PHA	process 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
QRM	quality risk management
RA	risk assessment
RCA	root cause analysis
SOP	standard operating procedure
TAMC	total aerobic microbial count
TFC	total fungi count

TLC	thin layer chromatography
URS	user requirements specifications
UV	ultraviolet-visible spectrophotometer

Part 2	Brief summary of the findings and comments
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1. Pharmaceutical quality system

A formal documented quality system was established, with procedures covering all expected key quality elements being in place. QA and QC departments were independent of production. Operations were specified in written form and GMP requirements were essentially being met. The procedures that were reviewed and discussed during the inspection were generally of a satisfactory standard. However, some delays in retrieving and presenting documentation were seen and it is recommended that the company improves in this area. Product and processes were monitored and these results considered during batch release. Regular monitoring and reviews of the quality of APIs and FPPs were being conducted according to documented schedules and procedures.

Product quality review (PQR)

The company had in place a procedure for performing product quality reviews. These reviews had to be performed according to a plan which was drafted at the beginning of the year and the reviews had to be prepared and approved within 3 months from the defined review period. CAPA in relation to observations identified during the previous WHO inspection were checked as well as the PQR of Artesunate 60 mg Powder for Injection. A review of deviations, OOS, OOT and CAPA included in the PQR was performed.

Quality Risk Management (QRM)

A procedure on performing risk assessment was in place. Failure modes and effects and criticality analysis (FMECA) was the preferred tool for conducting risk assessments. Other applicable tools were also described. CAPAs related to the observations identified during the previous WHO inspection were checked. It was noted that the company had performed root cause investigations and performed risk assessments highlighted in observations but did not adequately correlate observations in with similar operations. More specifically the company had performed a risk assessment on Artesunate FPP as a result of an observation from the previous WHO inspection, but it did not include the step of rendering Artesunate API sterile. A separate risk assessment was available, but it was not up to date. Appropriate CAPA were implemented and these observations are now considered as closed.

A risk assessment on operator gloves was performed and equipment for testing was bought and tests were implemented. In-House Specification for Sterile Surgical Gloves Powder Free was updated, Risk assessment on growth media sterilization was performed. Similarly a risk assessment on degradation of Sodium Bicarbonate during sterilization was presented.

Change and deviation management

The company had procedures in place for change and deviation management. The procedure on handling of changes adequately described the stages of initiation, evaluation, approval, implementation and review. Deviations were categorized as planned and unplanned and dealt based on their criticality. Root cause investigations were conducted and relevant CAPA were identified and implemented.

2. Good manufacturing practices for pharmaceutical products

In general, production operations followed defined procedures. Manufacturing processes were adequately defined and documented in BMRs and BPRs. Required resources were available, including adequate premises, equipment and utilities. Appropriately qualified personnel were employed. Qualifications and validations were performed according to prepared protocols.

3. Sanitation and hygiene

Premises and equipment were generally maintained at an acceptable level of cleanliness and they were appropriately labelled. There was a pest control programme in place.

Following the observation during the last inspection new garments were procured. New facilities for hand/foot washing and drying were introduced

4. Qualification and validation

The company had in place procedures for performing calibration and qualification of equipment. A VMP was available. The procedure and qualification of the HVAC system was spot checked. More specifically qualification of HVAC for filling room G24 (Grade A/B) as well as AHU-GF-06 were reviewed. The following qualification tests were performed in order to environmentally qualify the sterile facilities:

Air flow volume and air changes

Filter integrity

Differential Pressure

Temperature and Relative Humidity

Non-viable particles

Microbial monitoring

Airflow visualization

Recovery

Containment- Leakage Test

The Depyrogenation Tunnel requalification was performed in April 2018. Spot checks on the requalification test were performed

The procedure on cleaning validation of the vial filling line was reviewed. The procedure addressed critical cleaning, addition and removal of products, changes in cleaning methods.

5. Complaints

The company had in place a procedure to manage complaints. Corporate QA was responsible for assigning criticality and initially handling any complaint. Root cause investigations were carried out by the relevant site. Critical complaints were given priority in handling. Investigations were extended to other batches, products and processes if necessary. Potential counterfeiting was also taken into consideration during complaint investigations.

6. Product recalls

A procedure was in place for recalling products from the market. Recalls were managed by Corporate QA where criticality and urgency were classified. Notification measures were defined, and reconciliation had to be completed within specific timeframes. Mock recalls were conducted yearly on a rotational basis to cover all dosage forms and APIs.

1. Contract production, analysis and other activities

Production of Artesunate was not contracted out. IPCA had in place contracts with analytical laboratories but technical agreements were not reviewed during the inspection due to time constraints

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

Suppliers' audits and approvals were performed by the Ipca Corporate team of auditors. The relevant SOP described the process for qualifying and evaluating suppliers. An audit schedule was available. This evaluation took place quarterly.

9. Personnel

The organogram pertaining to Operations and Quality Assurance at Ipca Ratlam was adequate with clear separation between production and quality control. Reporting lines to Corporate Ipca Laboratories Ltd were properly indicated. Personnel had in general appropriately defined duties and responsibilities.

10. Training

Training was provided at pre-defined intervals and when procedures changed or were updated. Training records relating to SOP Sampling Procedure of Intermediates, In-Process and Finished Products were reviewed. Written assessments of trainings were not always performed. Similarly training on new equipment and SOP on handling of Pre-Sterilized Hand Gloves for Aseptic Area were checked. It included training of Operator Glove Integrity Test, and Wrapping Procedures of items to be Sterilised.

11. Personal hygiene

All personnel, prior to and during employment, had to undergo an initial health examination. Thereafter regular health examinations were carried out every year. Personnel conducting visual inspections had to undergo periodic eye examinations every six months. Personnel gowning procedure was appropriate and was generally followed. Instructions and pictorials to be followed were sufficiently clear when it came to personal hygiene. Operators working in the aseptic filling area were qualified periodically. SOP on Personnel Behaviour Inside Aseptic Area was updated as a result of an observation

12. Premises

Storage areas for warehousing of raw materials and finished product were of sufficient capacity. Temperature and humidity were monitored. There were areas for storing temperature sensitive materials. Receiving and dispatch bays were separated and were protected from weather conditions. In general changing rooms were designed as airlocks and used to provide physical separation of the different stages of changing. Changing rooms were flushed with filtered air. Premises were cleaned and disinfected according to written procedures. Fogging was used for sterile facilities. The layout of Pharma III ground floor, where Vial Manufacturing took place, indicated that the Change Room before one enters Grade C area where washing and sterilisation took place, was Grade D. This issue was resolved as part of CAPAs. Building IBD VIII was renovated by introducing new doors, new airlock and dynamic pass-boxes. In addition a new AHU was introduced supplying air to the non-classified corridor. The facilities where Artesunate API was manufactured, were briefly visited as well as different warehouses in order to have a comprehensive picture.

13. Equipment

The production equipment for sterile Artesunate API was dedicated for this product.

In general equipment assembly, maintenance and cleaning instructions were available and logbooks were maintained.

For the inspection of vials a semi-automatic optical inspection machine was qualified.

The integrity of the glove ports in the RABS were tested according to ISO standards. The relevant procedure was updated and testing equipment was purchased and qualified.

14. Materials

There was a procedure in place describing receipt and storage of raw materials. A check list was used for receipt of raw materials. Material stock and status were managed via an ERP system. A unique material code was assigned to each material in the system. Procedures for material sampling and dispensing were available. Temperature and Relative Humidity were monitored and controlled. In general, raw materials and packaging material for API manufacture were maintained in ambient temperature in the warehouse. Quarantine was applied until the materials were appropriately sampled, tested and released. At receipt the source of materials was checked against an approved supplier list. An ERP system was used to manage material stock. There were separate areas assigned for flammable materials

15. Documentation

A documentation system was in place. Procedures defined and supported manufacturing and quality control operations. In general documents were approved, signed and dated by appropriate responsible persons, reviewed and kept up to date. Specifications and testing procedures were available. The company had a system for implementing corporate and site procedures. Nevertheless, it was observed that some reports did not include definitive conclusions indicating acceptance/approval of the method/process/data. In addition some delays in retrieving and presenting documentation were experienced. It is recommended that the company improves in these areas.

16. Good practices in production

A visit to production areas was made in Building IBD- XII (Artesunate API), Building IBD – VIII 2nd floor (sterile Artesunate API), Building Pharma – III (Artesunate powder for injection, Sodium Bicarbonate powder solvent for injection, Sodium Chloride powder solvent for injection). At the time of inspection there were ongoing production operations. Areas inspected included sampling booths, dispensing areas, aseptically filling areas and primary and secondary packaging areas.

Pharma III (Ground Floor) Aseptically Filled Vials

The Vial Filling Line Media Fill protocol and report were reviewed. The Media used was Sterile Soya bean Casein Digestive Medium and Sterile Lactose. Grade A monitoring for Viable and Non-Viable Particle took place, during entire Media Fill exercise. Viable and Non-Viable Particles were also monitored in Grade B background before and after Media Fill.

Filling of Vials took place in room G – 24 containing a RABS unit surrounded by Grade B area. Grade B area was qualified to host 5 persons. The number of personnel was controlled by an entry log. Operators entering the aseptic filling room were appropriately qualified.

Vial sealing took place in Room G – 25; vials were transferred on a belt from Room G – 24 to G -25 under a Grade A laminar flow.

Isopropyl alcohol (IPA) containing bottles were used in Grade B area. The bottles were sterilised by autoclave and IPA filtered in LAF unit.

Pharma III Second Floor Ampoule Manufacturing

Holding of Ampoules before Terminal Sterilisation took place in Room S – 30. Batch trays were stored in the room where the autoclave was installed

17. Good practices in quality control

IPCA had established procedures for receipt and handling of samples in the laboratory. Logbook were maintained. Specifications for raw materials, packaging materials, bulk and finished products were available. Analytical methods were established and qualified. HPLCs were networked using laboratory software and data was maintained in a server. Stability Chambers were qualified annually and alarms in case of malfunction were installed. The Stability plan used to monitor stability samples, was presented

Part 3	Conclusion – Inspection outcome
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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, *Ipca Laboratories Limited, Ratlam India* 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
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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**
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 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-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. 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 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 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. 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

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