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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	Meditab Specialities Ltd.
Corporate address of manufacturer	Meditab Specialities Limited, Unit No. SB-901 & SB 902, Empire Tower Bulding, Gut No. 31, Cloud City Campus, Thane Belapur Road, Airoli, Navi Mumbai – 400 708
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Meditab Specialities Ltd. 352, Kundaim Industrial Estate Kundaim, Goa, 403 115 India
Inspection details	
Dates of inspection	17 -19 July 2019
Type of inspection	Routine
Introduction	
Brief description of the manufacturing activities	The site is specializing in the manufacture of tablets. No β-lactams, cytotoxics or hormones are manufactured on site. Stores, production, packaging and QC facilities are temperature and humidity controlled and manufacturing areas are provided with filtered air.
General information about the company and site	Meditab Specialities Pvt Ltd. is a Cipla associated company that was established in 1998. It is managed by a board of directors and the headquarters are located in Mumbai. The company has two facilities located in Satara and in Goa, specializing in the manufacture of tablets. The facility in Goa is located approximately 30Km away from Goa International Airport and 20Km from Panjim. The site operates under Cipla Corporate Quality Management System.
History	This was the fifth WHO inspection

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document reviewed including but not limited** • Organization Chart • Job descriptions for key personnel • Personnel training and hygiene • Product Quality Review • Quality Risk Management • Responsibilities of the quality units and production • Complaints and Recalls • Deviation control and change control • CAPA procedure • OOS and investigation • Material release • Self-inspection and vendor qualification • Validation and qualification • Equipment calibration • Data integrity • Sampling and testing of materials • Batch processing records • Materials management system • HVAC system **Site visited:** • Starting material warehouse • Tablet manufacturing operations • QC laboratories including chemical and microbiological • Stability chambers and retained samples area.
Restrictions	N/A
Out of scope	Products not submitted to WHO for Prequalification
WHO products covered by the inspection	NT003 Praziquantel Tablet 600mg HA352 Efavirenz Tablet, Film-coated 600mg HA353 Lamivudine 150mg tabs HA039 Nevirapine Tablet 200mg HA365 Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg HA060 Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg
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

A pharmaceutical quality system (PQS) was established, with Quality Manual, Policies and written procedures covering essential GMP principles for the site. The Quality Manual was presented and was briefly reviewed during the inspection. PQS and Quality Manual were under the umbrella of Cipla Corporate and QM was common and applicable to all Cipla Units and Associate Companies. The only copy of the QM was maintained by Quality Assurance. A Cipla corporate procedure for management review meetings was presented. The Management Review Coordinator was responsible for collecting all necessary information for quality review, organizing the meetings, tracking closure of open action items and maintain the management review reports. Management Review meetings were held monthly. The record of the most recent meeting was presented. Organization charts depicting the hierarchy within the company were available. Quality Assurance was independent from production and it was responsible for release or rejection of batches.

Batch release was performed according to a written. Two QA persons were qualified to perform batch release. A BMR was originally checked by the manufacturing department Head, and a completed checklist was sent to QA reviewer. Similarly, the QC responsible person had to complete the review of the analytical work and update the product status in the relevant database. QA reviewer was responsible for checking the BMR for completeness and accuracy.

Product quality review (PQR)

A Cipla corporate PQR procedure was in place describing the steps to verify consistency of existing processes, appropriateness of established specifications for starting materials, in process and finished products. For existing products Quality Assurance was preparing a PQR rolling plan at the end of the previous year. QA was also responsible for compiling PQR information and the relevant departments were responsible for reviewing and approving the pertinent parts of the PQR

The following PQRs were reviewed:

Product	Reporting Period
Nevirapine 200mg tabs	JUL 2017 – JUN 2018
Lamivudine 150mg tabs	MAR 2018 – FEB 2019
Lamivudine/Nevirapine/Zidovudine 150/200/300mg tabs	MAY 2018 – APR 2019
Praziquantel 600mg tabs	AUG 2017 – JUL 2018

Quality Risk Management (QRM)
A QRM procedure was available. Risk assessment tools were appropriately described. Ratings for severity, occurrence and detection were defined. RPN evaluation took place in two steps. Initially RPN was calculated by quantifying and multiplying severity by occurrence factors in order to identify severe events that were not detectable. If the initial calculation exceeded a set value, then this process was deemed critical and no further calculation would apply until a risk mitigation plan was implemented. For risks where calculations would derive values below the risk threshold value, detectability was used as an extra parameter in the risk assessment (second step). The risk assessment of the plastic container packaging line was reviewed.

Change and deviation management
The company had in place procedures for change and deviation management. The change request SOP was applicable to all changes relating to product, document, facility, equipment and any other system affecting the manufacture and quality of a product. Change requests were registered electronically. The SOP defined the persons who could initiate a change request as well as the persons to review, approve, implement and assess the adequacy of implementation. Changes were classified in three categories (major, moderate, minor) based on criticality and impact. A procedure for initiating and managing a change request using software was presented. Examples of 2019 registered changes were checked

A procedure on handling deviations was applicable to all production, quality control activities, processes and systems. Deviations were registered electronically. The head of the department was responsible for review and immediate action and QA was responsible for review of the deviation record and proposed CAPA. Deviations were divided to planned and unplanned and were classified in three categories (critical, major, minor), based on impact. Investigations and root cause analysis were carried out in accordance with a written SOP. The concerned department head along with QA and any concerned department heads were responsible for evaluating the deviation, recommend CAPA and assess their effectiveness according to a documented procedure. Review and trending of deviations took place in accordance with a written SOP. A backup process in case of software failure was defined. The deviation registers for 2019 were presented and examples of deviations were reviewed

CAPA management
The CAPA management procedure sufficiently described a system for conducting and documenting activities for remedial actions. CAPA were registered electronically.

Investigation of Out of Specification
OOS test results were handled according to two procedures depending on their nature (microbiological vs. laboratory non-conformance). The latter procedure was applicable both to OOS and OOT results obtained from physicochemical analyses. The procedures adequately described the registration, investigation, evaluation of non-conforming test results. Laboratory software was used to register and manage OOS and OOT results.

2. Good manufacturing practices for pharmaceutical products

Basic principles of good manufacturing practices were generally described and implemented. Manufacturing processes were adequately defined and documented in BMRs and BPRs. Line clearance were registered in BMRs and BPRs. Equipment requiring daily calibration were appropriately registered in logbooks. Required resources were available, including adequate premises, equipment and utilities. Instructions on use, cleaning and maintenance of premises and equipment were generally followed. Appropriately qualified personnel were employed. Several BMRs for were reviewed and were found complete. Line clearance documentation was included in the batch records; yields were appropriately calculated. Reconciliation of packaging material was documented.

3. Sanitation and hygiene

Premises and equipment were generally maintained at an acceptable level of cleanliness and they were appropriately labelled. Instructions on cleaning and storage of equipment were presented. Specifications for cleaning materials and uniforms were available. Mirrors were installed in change rooms along with pictorials for correct gowning. Hand washing basins and disinfectants were available in personnel change rooms.

4. Qualification and validation

The key principles of qualification and validation program were defined and documented in the Validation Master Plan. VMP followed the Cipla corporate guidelines. A list indicating qualification status of equipment was available. It was noted that small portable equipment (e.g. vibratory sifter, metal detectors, dedusters) were not included in the validation list. Requalification of several production equipment were reviewed and found adequate. Identified observations were appropriately addressed and closed out in the CAPA plan.

Requalification of the dispensary and compression rooms' HVAC systems were reviewed. Requalification took place annually. Temperature and relative humidity was within the established limits. Air changes were measured, recorded and found within limits. Recovery test was performed, and the set limit was met. Non-viable particles were measured. Differential pressures between adjacent rooms and terminal filters were measured and found within the established specifications. Microbiological requalification was also performed. Similarly, environmental requalification of the microbiological laboratory and LAF were reviewed.

The PW system trending report conducted during December 2018 – January 2019 was reviewed. The following parameters were trended and found within established limits: conductivity, pH, nitrates, TOC, total aerobic count.

Cleaning validation was performed according to Cipla's corporate procedure. The procedure described the methodology for assessing a product and for establishing the worst-case scenario. Swab and rinse sample collection methods were sufficiently described. PDE, Dose and 10ppm calculations were presented. The most stringent limits of acceptance criteria were used to derive the cleaning validation limits. The cleaning validation matrix and establishment of worst case product was briefly checked. Reports on toxicological assessment of three products having the lowest PDE value were reviewed. Equipment train was defined. Identified observations were appropriately addressed and closed out in the CAPA plan.

5. Complaints

The company had in place a Cipla corporate procedure on registering, investigating and monitoring complaints. Complaints were classified in two categories based on criticality. Complaints received by the manufacturing site had to be communicated to Cipla Corporate Quality Assurance who was responsible for logging the complaints electronically. The site was informed, and initiated investigations based on Cipla's instructions. Corporate QA was responsible for requesting the complaint samples. A cross-functional team was assigned to perform the investigations which depending on the initial assessment, could extend to other batches or products that might be affected by the same defect.

6. Product recalls

The company had in place a procedure describing measures for recalling products from the market according to Cipla corporate procedure. Site QA was responsible for escalating any issue that could potentially lead to a recall and for initiating a Quality alignment meeting. The final decision for recall was taken by Head of Cipla Global Quality Compliance and Systems. Recalls were categorized in three classes according to criticality and health impact and the depth of recall was defined. The recall coordinator was responsible for the oversite of the recall process. The records of a recall carried out in 2018 were reviewed and found adequate. The recall was categorized as Class III and the depth of recall was defined to depot level. Reconciliation took place and the recall was deemed effective. In general, mock recalls were initiated by Cipla Corporate QA on a rotational basis involving one Unit at a time, provided that no recall had taken place in the year. According to the technical agreement between the two companies, Cipla was responsible for the recall process and Meditab was to provide appropriate support according to Cipla instructions.

7. Contract production, analysis and other activities

The contract between Meditab and Cipla was presented. The contract covered manufacture of Cipla products in two Meditab sites (Satara and Goa). The contract was reviewed every 3 years. A table defining the responsibilities of the two parties was included in the agreement. Meditab was responsible for product release. Cipla was responsible for initiating product recall but the responsibility for the recall process and activities were shared between the two parties. Identified observations were appropriately addressed and closed out in the CAPA plan.

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

Self-inspections were not reviewed in detail due to time constraints. Suppliers were audited according Cipla's corporate SOP. Cipla was responsible for preparing an audit programme for all audits due in the year. The programme was reviewed every three months. In general API suppliers were audited every 36 months and excipient suppliers every 48 months. Auditors were appropriately qualified and their credentials and qualifications were stored electronically.

A procedure on qualification approval and rating of material suppliers was presented. Suppliers were initially qualified based on-site audit or documentation evaluation. A procedure for requalification of manufacturers was available. Although Cipla sites were audited they were excluded from the certification process, which was applicable to all other sites.

9. Personnel

Organization charts were available reflecting administrative structure. Job descriptions for key personnel were presented. Job descriptions of QA manager, Warehouse manager and Production manager were reviewed.

10. Training

Training was carried out according to Cipla's corporate SOP. Trainers were qualified and included in a qualified instructor list. Induction, continuous and on the job-training were available. Training effectiveness was assessed by oral tests, on the job and by written tests, records of assessment were presented. QA was responsible for establishing an annual training programme.

11. Personal hygiene

A Cipla corporate procedure on monitoring personal health and hygiene was available. Apart from pre-employment medical examination, all employees underwent annual medical examinations. Pre-employment medical examinations of three newly recruited temporary workers were reviewed. Instructions on handwashing and disinfection before entering production premises, gowning and hygiene behavior were described in SOPs. There was no handwashing basin in the visitors changeroom, but visitors were instructed to wash their hands before entering the production premises. Jewelry and beauty aids were not allowed in production premises. There was a procedure in place providing specifications and instructions on issue of uniforms for workers and visitors. Similarly, a SOP on entry and exit of visitors was available.

12. Premises

Generally, premises were located, designed, constructed, adapted, and maintained to suit the operations being carried out. The design of premises was logical and laid out in a manner to minimize the risk of errors and cross-contamination and permit effective cleaning and maintenance. The production area was laid out to allow production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels. Exposed surfaces were smooth, impervious and unbroken to minimize the shedding or accumulation of particles or microorganisms and permitted the repeated application of cleaning agents and disinfectants, where used. There were separate stores for raw materials, primary, secondary, tertiary packaging materials and for finished products. Dedicated cages for rejected and recalled products were located in the finished product stores. Temperature and relative humidity were monitored. A dedicated visitors' entry was found on the ground floor while personnel entered the premises from a change room on the 1st floor. Packaging material stores were located on the lower ground floor along with the packing material laboratory.

13. Equipment

Equipment was installed in a logical way to accommodate manufacturing processes. It was generally maintained in a good state of repair and each piece of equipment had a unique identification number. Calibration and preventive maintenance labels were placed on each critical equipment including balances and pressure gauges. They were found to be within the validity timelines for calibration and maintenance. Procedures for cleaning of each piece of equipment were available in the production area and records were maintained. There were separate log books kept for cleaning, usage and preventive maintenance of each equipment.

The pipework for potable and purified water were labelled and the direction of flow was indicated. Maintenance and sanitization of the PW system was reviewed. Sanitization of the loop took place weekly. RO columns and EDI were sanitized monthly. The UV lamp was changed based on operational hours. Logbooks for sanitization and preventive maintenance were presented.

Calibration of analytical balances and dispensary balances were checked. Identified observations were appropriately addressed and closed out in the CAPA plan

Calibration of temperature and relative humidity loggers in stability chamber were also reviewed. Preventive maintenance took place quarterly and registered in the relevant logbook. Spot checks on preventive maintenance and cleaning logbooks of plastic bottle packing line were made.

14. Materials

There were procedures in place describing receipt, storage and management of raw materials. A checklist was used for receipt of raw material. A database was used to register incoming material and manage existing stock. The principles FE-FO and FI-FO were built into the system. Appropriate storage conditions were maintained and monitored for excipients, packaging material, APIs and finished products. Sampling of raw and packaging materials was performed in accordance with a written SOP. It was noted that a sampling procedure dedicated to WHO PQ products was available. Rejected and recalled material and products were allocated caged bins in the finished product store room. Dispensed materials were placed in double bags and then metal containers which were stored in the production stage room for up to 10 days. Reconciliation of packing material took place in production and was verified by QA. Packaging material quantities returned to the warehouse were verified by warehouse personnel and in the database.

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. An electronic documentation system was used for managing documentation. A Cipla corporate procedure for the preparation of SOPs and Corporate Technical Guidelines was available. Templates used for establishing SOPs were described along with the process for approval and implementation.

16. Good practices in production

Manufacturing areas were visited. Floor plans were provided during the visit. Areas inspected included storage rooms, sampling and dispensing areas, granulation, compression rooms, coating rooms and primary and secondary packaging areas. At the time of inspection there were ongoing production operations. The production areas and equipment were kept in a good cleanliness level and were appropriately maintained. Temperature and humidity conditions as well as differential pressure between production rooms were controlled and monitored

17. Good practices in quality control

Quality control laboratories were separated from production areas. Chemical laboratories were visited as well as the separate areas where stability chambers were installed. The QC lab was well organized and equipped. Analytical equipment was installed in separate rooms and logbooks for use and maintenance of equipment were presented. Reference and working standards were appropriately stored. The validity of reference standards was checked every two months. Consumption of reference and working standards was monitored.

Stability studies were carried out in accordance with Cipla's corporate procedure. A stability programme was established and was managed electronically. Samples had to be withdrawn from stability chambers within three days of the target date and analyzed within two working days. Stability studies of WHO PQ products were reviewed and found adequate Critical quality attributes remained constant during the studies.

The microbiological laboratory was briefly visited. Culture media and microorganisms including inhouse isolates were available. Relevant certificates were presented. Growth promotion was performed for every growth medium batch and whenever a new container was opened. Negative controls were also carried out.

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, ***Meditab Specialities Pvt. Ltd.*** located at ***352, Kundaim Industrial Estate, Kundaim, Goa, 403 115, 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 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