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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer and address	**Delta Finochem Pvt. Ltd** Gate no. 350, Village Wadivarhe , Tal-Igatpuri dist-Nashik, 422 403 India North latitude: 19.98º East longitude: 73.8º D-U-N-S: 91-844-4399
Manufacturing blocks	• Block A and Block A Clean Room • Block C • Block E
Corporate address of manufacturer	Plot No.: 121, M.I.D.C Area, Satpur, Nashik - 422007. Maharashtra, India
Inspected site	
Address of inspected manufacturing site if different from that given above	As above
Manufacturing license number	25/NKD/92 & Form – 25 for manufacturing intermediates and APIs.
Inspection details	
Dates of inspection	11 – 13 September 2017
Type of inspection	Initial
Introduction	
Brief summary of the manufacturing activities	The manufacturer was involved in the manufacturing, packaging, labeling, testing and storage of intermediates APIs.
General information about the company and site	History of the company: • 1978 – Formation of Delta Industries • 1978~1994 – Manufacturing of Bromides & other Intermediates @ Plot # 121, MIDC- Satpur, Nasik • 1994 – Started Manufacturing of Phase Transfer Catalyst @ Plot # 121, MIDC-Satpur, Nasik • 2000 – Date of Incorporation of Delta Finochem P.Ltd

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- 2003 – Move to the New Facility at Wadivarhe (Gat # 350, Village Wadivarhe,Taluka-Igatpuri,Dist-Nasik) for Manufacturing of Phase Transfer Catalyst
- 2003 - Plot # 121, MIDC-Satpur, Nasik converted in to the Research Centre
- 2003~ 2004 – Started Manufacturing Intermediates
- 2006~2007 – Started Manufacturing API
- 2012 ~ 2013 – Received DSIR Certification of the Research Centre
- 2012 ~ 2013 – Received GMP Certification of Wadivarhe (Gat # 350, Village Wadivarhe,Taluka-Igatpuri,Dist-Nasik) unit.

Manufacturing Unit II was located at Gonde, about 5 kms from the Wadiwarhe Site. Unit 2 was used for distillation of Organic Bromides and Fine Chemicals.
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<tr><td>History</td><td>

This was first WHO inspection

The site was inspected by the following authorities:

<table>
<tr><th>Authority</th><th>Scope of inspection</th><th>Dates of inspection</th></tr>
<tr><td>Central Drugs Standards Control Organization, India CDSCO</td><td>19/10/2012</td><td>GMP inspection</td></tr>
<tr><td>CDSCO</td><td>14/03/2013</td><td>GMP inspection</td></tr>
<tr><td>CDSCO</td><td>27/08/2013</td><td>GMP inspection</td></tr>
<tr><td>CDSCO</td><td>03/09/2015</td><td>GMP inspection</td></tr>
<tr><td>Maharstra, India FDA</td><td>27/10/2016</td><td>Vigilance visit</td></tr>
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<tr><td>Brief report of inspection activities undertaken</td><td></td></tr>
<tr><td>Scope and limitations</td><td></td></tr>
<tr><td>Areas inspected</td><td>

- Pharmaceutical Quality System
- Documentation system
- Production System
- Facilities and Equipment System
- Laboratory Control System
- Packaging/labelling System
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<tr><td>Restrictions/out of scope</td><td>Microbiological laboratory</td></tr>
<tr><td>Abbreviations</td><td>

<table>
<tr><td>AHU</td><td>air handling unit</td></tr>
<tr><td>ALCOA</td><td>attributable, legible, contemporaneous, original and accurate</td></tr>
<tr><td>AQL</td><td>Acceptance quality limit</td></tr>
<tr><td>API</td><td>active pharmaceutical ingredient</td></tr>
<tr><td>APQR</td><td>annual product quality review</td></tr>
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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
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
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
TOC	Total organic carbon
URS	user requirements specifications
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WFI	water for injection
WS	working standard

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

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 management of regulatory inspections, serious GMP deficiencies, product defects and related actions.

The traceability of records and documentation system were satisfactory.

Product Quality Review (PQR)

The SOP "Procedure for generation of annual product quality review (APQR)" was discussed. According to the SOP an APQR shall be prepared for a product having more than 5 batches during the year.

APQR covered but was not limited to:

- Number of intermediates and API batches manufactured
- Review of finished product dispatch details
- Review of critical in-process control and critical API test results
- Review of quality of batches
- Review of yield details
- Review of deviations, change controls, rejected materials
- Review of complaints
- Review of recalls, reprocessed and reworked batches
- Review of returned batches
- Review of CAPAs
- Review of stability and trends
- Review of critical raw materials vendors
- Review of OOS/OOT
- Review of validation packages

Environmental monitoring (EM) trends and purified water system trends were separate documents.

PQR was performed annually and according to the SOP should be completed by the end of February of the following year.

PQR of PRAZIQUANTEL for 2016 and 2015 were reviewed and discussed.

Quality risk management (QRM)

The SOP "Procedure for quality risk management" was discussed. According to the SOP QRM was applicable:

- Each stage of manufacturing process
- Inspection
- Packaging /distribution of products
- GMP system

Tool specified in the SOP for RM was:

- Failure modes and effects analysis (FMEA)
- Cause and effect diagrams
- FTA
- HACCP
- HAZOP
- PHA
- Risk ranking and filtering

As per company directives applied tools were FMEA, Ishikawa diagram and brain storming. Scoring from 1to 5 was used for RPN calculations.

Management review (MR)

The SOP "Procedure for conducting management review meeting" was discussed. According to the SOP MR shall be comprised every six months. According to the SOP the following items should be covered by MR:

- Review of previous MR meeting minutes
- Review of non-conformities raised during system audit
- Review of customer satisfactory survey/feedback/complaints
- Review of process performance, product conformity
- Review of status of CAPA
- Review of Quality policy, objectives and their status
- Review of resources
- Review of training records
- Review of recommendations for improvements
- Any other issues

MR minutes were discussed.

Deviations

The SOP "Handling of deviations" its flow chart and register were discussed. Deviations were classified as:

- Critical
- Major
- Minor

Minor deviations were renamed "incidents" and were handled separately.

A system of "5 why`s" and Ishikawa diagram were applied for root cause investigations. QRM shall be applicable to critical deviations. Deviation registers were maintained product specific. Deviations should be closed within 30 working days.

A Deviation number and short explanation of the deviation was recorded in related batch processing record.

Corrective actions and preventive actions (CAPA)

The SOP "Procedure for corrective and preventive action" and register for 2017 were discussed. The SOP was applicable but not limited to:

- Deviations/non-conformances
- Complaints
- OOS
- Self-inspection/external audits
- APQR
- Regulatory issues

According to the SOP, CAPAs were proposed by each concerned department and evaluated by QA and closed within 45 working days. CAPA related to the unplanned deviation XX was discussed.

Change control (CC)

The SOP "Change control procedure" and registers for 2016 and 2017 were discussed. CCs were classified by QA department as:

- Minor
- Major

- Permanent
- Temporary

CC registers were maintained:

- Product wise
- General CC
- Document changes

Changes were initiated by each concerned department and approved by QA. Change Controls recorded in 2016, were reviewed and discussed.

Self-inspection

The SOP "Procedure for Self-inspection" was discussed. Self-inspections were performed by a cross functional team. According to the SOP all departments should be audited once in six months. Self-inspection schedule for 2016 and 2017 was presented to the inspectors. Cross checks showed that schedules were followed.

Self-inspection observations were classified as:

- Critical
- Major
- Minor

The Self-inspection team members' qualification files were available.

Audits were performed following departments' check lists. Shelf inspection check list for quality control department was discussed. CAPAs were submitted by the audited department and evaluated by QA. Follow-up was performed by QA.

Data integrity

The SOP "Data integrity policy" was discussed.

Complaints

The SOP "Handling of customer complaints" and register for 2016 were discussed. No complaints were registered in 2017. Complaints were classified as:

- Critical
- Major
- Minor

- Quality related
- Non-quality related

Recalls

The SOP "Procedure for recall" was discussed. There were no product recalls in the Company history. The following types of recalls were specified in the SOP:

- Class A
- Class B
- Class C
- Statutory recall
- Voluntary recall

According to the SOP mock recall should be performed once in two years.

Supplier qualification

The SOP "Procedure to evaluate and qualify the vendors" and approved suppliers list were discussed. The SOP was applicable for raw and packaging materials vendors.

Critical raw materials and primary packaging materials vendor's requalification audits were performed every 3 years. Non-critical materials vendors were qualified against a questionnaire.

Vendor audit schedule was presented to inspectors; spot checks showed that the schedule was followed.

Two manufacturers audit reports were discussed.

Contracts

The company had contracted out micronization process and particle size distribution analysis.

Validation Master Plan (VMP)

The SOP "Validation master plan procedure" was discussed. The VMP was applicable for:

- Production systems
- Engineering and utilities systems
- Analytical laboratory / QC systems

Personnel

The current organization chart of the company was available. In general the company had a sufficient number of personnel with responsibilities according to their respective units and departments.

According to the company presentation, the number of full time employees was 221

Personnel were wearing clothing suitable for the manufacturing activities.

Training

The SOP "Training" and training schedule for 2017 were discussed. This SOP was applicable for all employees training. The following types of training were described:

- Induction new recruiter – freshener (oral evaluation)
- New recruits – experienced (oral evaluation)
- On job training / functional training (oral evaluation and written evaluation yes/no/true/false)
- GMP (written evaluation yes/no/true/false)
- Safety training (written evaluation yes/no/true/false)
- Ongoing training (group discussion)
- Self-inspection auditors training (oral)
- Remedial training (oral evaluation and written evaluation yes/no/true/false)
- Training for operator persons
- Post training evaluation

Training records were kept in HR and or concerned departments.

The SOP "Analyst qualification" was discussed. Coded sample was given to analyst under qualification. Analyst had to perform triplicate analysis, RSD between triplicates were specified: for assay tests NMT 1 %, for RS tests NMT 5 %.

Analysts were requalified every 3 years.

A number of employees and analysts training files were discussed.

Job responsibilities for the QC manager and assistant manager, QC executive officer and chemist were checked.

The SOP "Employees medical checks-up and personal hygiene" was discussed. According to the SOP all personnel working in the company shall undergo medical examination annually.

2. Documentation system

Documents related to the manufacture of intermediates and APIs were prepared, reviewed, approved and distributed according to written procedures.

The following, but not limited, documents were discussed:

- "Procedure for initiation, approval, distribution control, storage, review, retention of documents & records". Documents related to batch production/control were retained 1 year after expiry date of the batch. Documents related to the transfer of technology, process development, scale ups, DMFs, stability data, distribution records etc. were retained for the product life time.
- "Product release for sale"
- "Handling of batch production record"
- "Reprocess procedure"
- "Rework procedure" It was explained that according to the company policy reworking of batches was not performed
- "Procedure for batch numbering, BPR numbering & assigning product code"
- "Procedure for label rolls handling"
- "Handling of returned products"
- "Procedure for preparation of certificate of analysis"
- "Procedure for operation and cleaning of reactors Glasslined (GL)/stainless steel (SS)"
- "Procedure for in process sampling"
- "Procedure for the cleaning of clean room filters"
- "Procedure for the qualification and the requalification of clean rooms"

If there were no changes, documents review period was three years. Documents were stored in QA archive in mobile compactors.

3. Production system

In general, production operations followed defined procedures. Process flows and routes of synthesis were available. Deviations from procedures were recorded; major deviations were investigated. Access to production premises was restricted to authorized personnel. Weighing and measuring devices were of suitable accuracy for the intended use. The processing status of major units of equipment was indicated.

Manufacturing operations of product under the scope of inspection were carried out in dedicated blocks.

At the time of the inspection, process validation was not completed.

4. Facilities and equipment system

The following areas were inspected:

- Warehouse for raw materials; intermediates, packaging materials and final products
- Solvent tank farm
- Solvent warehouse
- DM Water Plant
- Manufacturing block E
- Manufacturing block C
- Manufacturing Block A including pharma area
- QA documentation room including label printing
- Laboratory facilities

Buildings and facilities used in the manufacture of intermediates and APIs were located, designed, and constructed to facilitate cleaning, maintenance and operations as appropriate to the type and stage of manufacture. Facilities were designed to minimize potential contamination. Adequate space was provided for orderly placement of equipment and materials to prevent mix-ups and contamination. Generally the permanently installed pipework was appropriately identified.

QCL premises were separated from manufacturing facilities. Stability chambers were located in QCD.

Microbiological laboratory was recently constructed and at the time of the inspection equipment/utilities were under qualification.

Utilities

Demineralized water (DM)

The SOP “Procedure for microbial analysis of water” and DM trends for 2016 were discussed. SCD media was used for Total viable bacteria counts (TVBC). Alert and action limits were established.

HVAC system

Re-circulated air, generated by 9 air handling units was supplied to clean rooms located in Block A. Terminal HEPA filters H13 were installed in the rooms. G4, F5 and F9 filters were cleaned weekly. Pressure differentials between G4, F5 and F9 filters were checked and recorded daily using a manually system.
HEPA filters integrity tests were contracted out and performed annually.

Environmental monitoring (EM)

The SOP “Procedure for area count by settle plate method” and EM trends for clean rooms, block A were discussed. Alert and action limits were established.

5. Laboratory control system

Laboratory areas were separated from production areas. Laboratory was operating on 3 shifts continuously. Samples were received via pass box and registered in separate registers for raw materials, intermediates, and finished products.

The following sampling SOPs were discussed:

- "Sampling and release of the raw materials and intermediates"
- "Sampling and release of the packaging materials"
- "Sampling and release of the finished goods (API)"

The SOP "Reserve samples maintenance and quality review" was discussed. Reserve samples were stored in the same packaging system in which the API is stored or in one that is equivalent to or more protective than the marketed packaging system. Each API batch should be retained for one year after the expiry date of the batch assigned by the manufacturer; or for three years after distribution of the batch, wherever is the longer.

The SOP "Procedure for out of specification results", its flow chart and registers for 2016 and 2017 were discussed. There were separate laboratory incidents log books. According to the verbal explanation laboratory incidents were as an example: system suitability failure, mistaken injection volume, wrong injection sequence, leakage of column etc. It was discussed that there should be SOP describing procedure how to deal with laboratory incidents (documents / instruments / analysis related).

A number of OOS investigation reports were discussed.

The SOP "Working standard evaluation" was discussed. Working standards (WS) were qualified against pharmacopoeia standards. WS were dispensed in single use vials. It was noted that WS dispensed was at the time the LAF was under installation. Reference standards were stored in a commercial type fridge, what was not equipped with an alarm system. Temperature (T) was manually recorded once per day. Usage of reference standards was traceable.

There were two stability chambers available in laboratory for:

- Accelerated stability studies
- Long term stability studies (30 °C and 65%)

T and RH in the chambers was recorded every hour by commercial software and checked once in 24 hours. It was noted that the third stability chamber was under installation. Stability chambers were equipped with audible alarm.
The SOPs "Audit trail review of analytical data for chromatographic / non chromatographic systems", "Chromatographic practice" and "Backup and restoration of electronic data for stand-alone systems and creation of data path" were discussed.

Specimen signature log was presented to the inspectors.

During the laboratory inspection a number of instruments, log books and calibration records were checked.

Analytical balances were verified daily using 5 standard weights and calibrated monthly for:

- Repeatability
- Weighing profile
- Accuracy
- Sensitivity
- Eccentricity
- Linearity

HPLC grade water was purchased from outside the laboratory.

6. Packaging/labelling system

Packaging / labelling operations were not inspected.

The SOP “Procedure for label rolls handling” and SOP/QAD/026/01 “Procedure for the handling of damaged labels” were discussed.

Roll labels were stored in mobile compactors.

PART 3

CONCLUSION

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, as well as corrective actions taken, the API under prequalification process manufactured at Delta Finochem Pvt. Ltd **(**Block A, Block A Clean Room and Block C) located at Gate no. 350, Village Wadivarhe, Tal-Igatpuri dist-Nashik, 422 403 India was considered to be manufactured in compliance with applicable sections of WHO GMP for Active Pharmaceutical Ingredients.

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 used for assessing compliance

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-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/
   Short name: WHO TRS No. 986, Annex 2

3. 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

4. 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/

5. 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

6. 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

7. 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

8. WHO Good Practices for Pharmaceutical 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. 957, Annex 1
   http://www.who.int/medicines/publications/44threport/en/

9. 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 3
   http://www.who.int/medicines/publications/44threport/en/

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. Fiftieth 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. Fiftieth 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. 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