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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
API manufacturer (Zinc Sulfate monohydrate)

<table>
<tr><th>Part 1</th><th>General information</th></tr>
<tr><td>Manufacturers details</td><td></td></tr>
<tr><td>Company information</td><td></td></tr>
<tr><td>Name of manufacturer</td><td>Canton Laboratories Pvt. Ltd.</td></tr>
<tr><td>Corporate address of manufacturer</td><td>110-A&B, GIDC Makarpura, Vadodara 390010
INDIA
Webpage: www.cantonindia.com
Telephone: +91-265-2638084 (4 Lines), 2638001
Facsimile: +91-265-2631950
info@cantonindia.com</td></tr>
<tr><td>Inspected site</td><td></td></tr>
<tr><td>Address of inspected manufacturing site if different from that given above</td><td>Survey No. 350, Village Mujpur,
Taluka Padra, Vadodara – 391440
Gujarat, INDIA

latitude : 22.251658
longitude : 73.003857</td></tr>
<tr><td>Unit / block / workshop number</td><td>Plant II, building I
• Line 2, 3 and 5</td></tr>
<tr><td>Manufacturing license number</td><td>
<table>
<tr><th></th><th>License No.</th><th>Issuing authority</th><th>Valid up to</th></tr>
<tr><td>Factory License</td><td>20046</td><td>Directorate, Industrial safety and Health, Gujarat</td><td>31st Dec 2018</td></tr>
</table>
</td></tr>
<tr><td>Inspection details</td><td></td></tr>
<tr><td>Dates of inspection</td><td>18 – 20 July 2016</td></tr>
<tr><td>Type of inspection</td><td>Initial inspection</td></tr>
<tr><td>Introduction</td><td></td></tr>
<tr><td>Brief summary of the manufacturing activities</td><td>The company is engaged in manufacturing and marketing of APIs, mineral fortifiers, food additives and specialty chemicals.
The company manufactures various products, such as pharmaceuticals, food, animal healthcare, Reagent etc.
In the context of APIs of medicinal products, the substances produced can be</td></tr>
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	considered as atypical actives.
General information about the company and site	Established in 1981, Canton is manufacturer in the field of Fine/Specialty high purity chemicals (mostly inorganic substances) having four manufacturing facilities in Baroda, western India. The company regularly exports products to USA and to various countries. The company is managed by the Board of Directors. Canton has a distribution network with Warehouse backup at New Jersey, USA. Canton India has two manufacturing sites: Plant I in Makarpura, Vadodara, and Plant II in Mujpur, Vadodara. Based on experience of over 3 decades in manufacture/ purification of Pharmaceuticals, Food additives, Mineral Fortifiers and Speciality chemicals, Canton Laboratories Pvt. Ltd. has built a new manufacturing facility in Mujpur, 27 km away from main city. The total area of this site is about 19332 m^2 with a built-up area of approx. 9104 m^2; the site was commissioned in middle of 2015. The Mujpur site has two manufacturing blocks; each one having five independent manufacturing lines with total segregation from each other from the start of the manufacturing process, all the way through to the packaging of the finished product. All the lines have similar equipment. Entire manufacturing operation at this site is designed to have segregation and contamination controls through controlled environment. With regards to Zinc sulfate monohydrate for medicinal products, the Company stated that only Plant II will be used for the production. The Company also stated that there is no exchange/transfer of Zinc Sulfate Monohydrate between Plant I and Plant II. The Company had decided to create a separate documentation for Plant II. Numbering and version control of documents was managed on Plant II level. Therefore, most SOPs at Plant II carried version numbers 00 or 01 (although the relevant activities may have be conducted in Plant I for several years). Till the date of inspection, only Building I had been taken into use. Production started in Building I in the second half of 2015. At the time of inspection, three lines out of five were considered by the site as operational: No 2, 3, 5.
History	This was the first WHO inspection at the site and first inspection of the Company. The site had been inspected by the local food and drugs authority and audited by the local accreditation body.

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	License No.	Issuing authority	Valid up to
GMP Certificate	S-GMP/l 6041069	FDCA, Gujarat	6th Apr 2018
Drug license	G/25/2112	FDCA, Gujarat	9th July 2020
FSSAI	10714024000268	Food and Drugs control administration, Gujarat state (Food safety department)	16th June 2019
FSSC 22000	IND15.2684 U	Bureau VERITAS, accredited by UKAS	25th Oct 2018
GLP License	Certi/GLP/Canton/2016/42152/B	FDCA, Gujarat	6th Apr 2018
Pollution Control Consent	AWH-67203	Gujarat Pollution Control board (GPCB)	9th Oct 2019
HALAL certification	04/15/0164/009/17/0516/153/1	Halal Committee Jamiat Ulama-E-Maharashtra	4th May 2017
Kosher certification	SKRMX7JE64X	Star-K Kosher	31st Mar 2017

Brief report of inspection activities undertaken	
Scope and limitations	
Areas inspected	Production Building I • Line 2, 3 and 5 Quality Control Warehouses Water system
Restrictions	N/A
Out of scope	Building II was not inspected as till the date of inspection manufacturing operations in this building were not carried out
WHO product numbers covered by the inspection	APIMF146 Zinc sulfate monohydrate used for • DI004 Zinc (as sulfate) Tablet, Dispersible 20mg • DI005 Zinc sulfate Tablet, Dispersible 20mg

Abbreviations

AHU	air handling unit
ALCOA	attributable, legible, contemporaneous, original and accurate
API	active pharmaceutical ingredient
APQR	annual product quality review

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AAS	atomic absorption spectroscopy
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

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PQR	product quality review
PQS	pharmaceutical quality system
QA	quality assurance
QC	quality control
QCL	quality control laboratory
QMS	Quality management system
QRM	quality risk management
RA	risk assessment
RCA	root cause analysis
RH	relative humidity
RM	raw materials
RS	reference standard
SAP	system applications products for data processing
SFG	semi-finished goods
SOP	standard operating procedure
STP	standard test procedure
T	temperature
TAMC	total aerobic microbial count
TFC	total fungal count
TLC	thin layer chromatography
TMC	total microbial count
URS	user requirements specifications
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan
WS	working standard

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

Brief summary of the findings and comments

1. Quality management

Principles

In general, a system for managing quality was established, documented and implemented. The quality unit was independent of the production department. The person responsible for release of intermediates and APIs was specified. Deviations from established procedures were documented and explained. Materials were released after quality unit satisfactory evaluation.

Internal audits (self-inspection)

The SOP "Internal audit" and schedule were discussed. The following departments were subjects of the self-inspection:

- QA
- QC
- Manufacturing & packaging

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- Purchase
- Human resources
- Personnel and administration
- Food safety

Product quality review
The SOP "Annual product review" was discussed.
PQR for 1st April 2014 till 31st March 2015 was discussed. The PQR discussed was for Zinc sulfate monohydrate manufactured at Plant I, as PQR for inspected Plant II was not yet available. According the SOP, the PQR will be prepared for a calendar year.

Quality risk management
The SOP "Risk management" was discussed. RPN (scoring 1 – 10) calculation examples were given in the SOP. Process wise hazard identification & risk analysis was discussed. RA included RM, water and all process steps, storage of finished products, access control, hygiene and waste.

Batch release
The SOP "Release of finished product" was discussed. Finished product release was responsibility of QA Head / designee.

Manufacturing record
The SOP "Batch manufacturing record" was discussed. Complete batch manufacturing record review was responsibility of Head QA / designee and was carried out according to the check list.

Batch numbering
The SOP "Assignment of batch number" was discussed.

The SOP "Finished product coding" was discussed.

2. Personnel
According to the site master file and company presentation, the site employed approximately 40 full time employees working on site.

Job descriptions
The following job descriptions were discussed:
- "Roles and responsibilities of Head QC"
- "Roles and responsibilities of Executive QA"
- "Roles and responsibilities of Head QA":
- "Roles and responsibilities of Executive QC"
- "Roles and responsibilities of Head manufacturing / packaging"

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Personnel qualifications
There were an adequate number of personnel qualified to perform and supervise the manufacture of APIs and other ingredients.

Personnel hygiene
Acceptable sanitation habits were observed on site. Personnel were wearing clothing suitable for the manufacturing activity they were involved. Smoking, eating, drinking, chewing and the storage of food was restricted to certain designated areas separate from the manufacturing areas.

Training
The SOP "Training" and workers training schedule were discussed. This SOP was applicable to employees and workers. Training evaluation was carried out by oral questions and written tests (objective).
The SOP "Analyst qualification" was also discussed.

Consultants
One consultant was used by the site. Agreement with the consultant and his experience (CV) was provided.

3. Buildings and facilities

Design and construction
Buildings and facilities had adequate space for the orderly placement of equipment and materials.
Laboratory areas and operations were separated from production areas.

Building I had five independent, physically segregated production lines, including their own "controlled areas". Independent entry and exit routes were provided. All facilities and production lines are multi-product.

Utilities
AHUs were provided for each "controlled area". 100 % fresh air was used. Primary filters were 10 micron filters; final filters were 5 micron filters and were installed terminally. The SOP "Operational maintenance of AHU" was discussed.

Water
Source water was obtained from bore well. Source water was passed through sand and carbon filters and 1st RO. 1st RO water was collected in a storage tank and subsequently was passed through 2nd RO followed by mixed bed. These stages were performed in a separate building. After the mixed bed the water was considered as process water. It was transferred via pipeline to the SS storage tank in the production unit. From the SS tank, the water passed a UV unit and was distributed via SS loop at ambient T.
SS water storage tank and loop were sanitized weekly by hot water (about 75 ºC ± 5ºC at the return loop) for 1 hour.

In-house specifications were available for different classes of water (source water, RO-I, RO-II, process water).

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Water system qualification Phase I and II trends were discussed. Phase III was under qualification.

Containment
Highly sensitizing materials were not manufactured on site.

Lighting
Adequate lighting was provided in to facilitate cleaning, maintenance and proper operations.

Sanitation and maintenance
Buildings used in the manufacture were maintained and kept in clean conditions. Written procedures were established for equipment/premises cleaning.

4. Process equipment

Design and construction
Equipment used in the manufacture was of appropriate design and adequate size, and suitably located for its intended use. In general, major equipment such as reactors and centrifuges were appropriately identified.

Equipment maintenance and cleaning
Schedules and procedures were established for the preventive maintenance of equipment. The SOP "Preventive maintenance" was discussed. PM schedule for 2016 was presented to the inspectors.

Calibration
Control, weighing, measuring, monitoring and test equipment that was critical were calibrated according to written procedures and an established schedule. Records of calibrations were maintained. The current calibration status of critical equipment was known and verifiable.

Computerized systems
Not used in production / laboratories.

5. Documentation and records

Documentation system and specifications
Documents related to the manufacture were prepared, reviewed, and approved. Specifications were established and documented for raw material, intermediates and finished products. Acceptance criteria were established and documented for in-process controls.

Equipment cleaning and use record
Records of major equipment use, cleaning and maintenance were available.

Records of raw materials, intermediates, API labeling and packaging materials
Some records were spot-checked.

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Master production instructions
Master production instructions had been established and appropriately approved. Master formula record for Zinc sulfate monohydrate was discussed.

Batch manufacturing records
The Batch Production Record for Zinc sulfate monohydrate validation batches and routine production batch were discussed.

Laboratory control records
According to the Master formula during the process samples were collected for in-process tests.

6. Materials management

Vendor management
Approved suppliers list for staring material and packaging material was presented to the inspectors. According to the approved suppliers list there were three approved manufacturers of the key starting material (KSM) and two suppliers.

The SOP "Vendor management" was discussed. According to the SOP manufacturers audits were optional, usually periodic "paper based" evaluation was carried out of the following parameters:

- Quality
- Quantity
- Timely delivery
- Complaint situation & handling of complain
- Documentation & response time in case of regulatory changes

It was noted that KSM zinc sulfate heptahydrate manufacturer audit was carried out in April 2016. According to the audit report, the company manufactures only one product: zinc sulfate heptahydrate.

General controls
In the warehouse, materials were managed manually. Separate warehouses were provided for starting materials, packaging materials and finished products.

Receipt and quarantine
Materials were held under quarantine until they were sampled, tested and released for use.

Sampling and testing of incoming production materials
Containers from which samples were withdrawn were marked to indicate that a sample has been taken. Sampling and dispensing of key starting materials and primary packing materials were carried out in the warehouse in separate room, under RLAF.

Storage
Finished products warehouse was monitored for T and RH. T mapping report for finished product store I was discussed.

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7. Production and in-process controls

Production operations

Two identical buildings were provided for production activities. During the inspection production activities were carried out in Building I, Building II was not in use and was not inspected.

The Company stated that organic solvents are not used in the production; processes are water based; for some substances acids are added. The same applied to cleaning.

In-process sampling and controls

Some in-process controls were carried out in production area only (visually) and other in-process controls were carried-out in the Quality control laboratory.

Blending batches of intermediates or APIs

The draft SOP "Blending of various approved batches" was discussed. The expiry or retest date of the blended batch will be based on the manufacturing date of the oldest tailings or batch in the blend.
The Company stated that the finished batches of Zinc sulfate monohydrate had not been blended so far.

Technology transfer

Zinc sulfate monohydrate production process was transferred from Makarpura plant to Mujpur plant. Technology transfer package contained the set of documents.

8. Packaging and identification labelling of APIs and intermediates

Packaging materials

Primary packaging materials were stored in the warehouse.

Label issuance and control

Finished product labels were generated and controlled by QA.

Packaging and labeling operations

Not carried out during inspection

9. Storage and distribution

Warehousing procedures

Facilities were provided for the storage of all materials. Released and rejected materials were stored separately. Quarantine areas were identified.

Distribution procedures

Finished products were released for sale after QA approval.

10. Laboratory controls

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Plant I laboratory had been used in relation to production conducted in Plant II - in the scope of development and validation, but routine quality control of Zinc sulfate monohydrate was performed on site, in the laboratory of Plant II.

General controls
In Plant II, only simple chemical tests; compendial and non-compendial were used for routine testing of starting materials, in-process and finished products.
The specification for Zinc sulfate monohydrate does not include microbiological testing.
Microbiological monitoring relates to water and controlled areas.

Testing of intermediates and finished products
Testing followed approved STPs.

Certificates of analysis
CoA were issued were issued for finished products. Analytical reports were available for all in-process tests.

Stability monitoring
The SOP "Stability" was discussed. Stability conditions were following:

- T 40 ºC ± 2 ºC, RH 75% ± 5%

long term:

- T 25 ºC ± 2 ºC, RH 60% ± 5%
- T 30 ºC ± 2 ºC, RH 65% ± 5%
- T 30 ºC ± 2 ºC, RH 75% ± 5%

Stability schedule (log book) was presented to the inspectors and spot checks showed that schedule was followed.

Retest dating
Retest date for Zinc sulfate monohydrate was based on stability studies and defined 5 years.

Reserve/retention samples
Reserve/retention samples were stored in market simulated packaging, samples log book was maintained.
Samples were stored for the period: retest date + 1 year.

Out of specification
The SOPs "Out of specification" and "Out of trends" were discussed. As per the SOP, OOT based on statistical calculations, but as yet, no limits were established for Zinc sulfate monohydrate.
Separate procedures and logs were maintained for OOS and OOT; the Company may wish to review this arrangement for practicality and better traceability.

Microbiology laboratory
Sterilization Autoclave's Validation had been outsourced.

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11. Validation

Validation policy

Validation approach was explained in VMP. Re-validation criteria's were specified.

Qualification

Equipment qualification was established. PQ was considered as part of process validation.

Process validation

The Batch Production Record for Zinc sulfate monohydrate validation batches was discussed. Process validation report of zinc sulfate monohydrate was discussed. Validation was carried out on production Line No.5.

Periodic review of validated systems

At the time of the inspection, the water system phase I and II were completed and phase III was in progress. All AHUs have been qualified and validated. AHUs validation was carried out in January 2016; next validation was scheduled in January 2017.

Cleaning validation

Protocol for cleaning validation was discussed. Worst case approach was used – calcium carbonate (insoluble in water) had been selected as the worst case.

Validation of analytical methods

SOP "Analytical method validation / verification" was discussed. Analytical methods validation was carried out for finished products. Compendial methods verification was carried out.

Hold time studies

Hold time studies protocols for wet product and cleaned equipment were discussed.

12. Change control

The SOP "Change control system" was discussed. Changes were classified as:

- Minor
- Major
- Critical

The SOP "Customer notification" was discussed. The SOP defined cases when customers should be notified for example:

- Change to facility
- Change to process
- Change to equipment
- Confirmed failure during stability studies / retained sample analysis
- etc.

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CC register for 2016 was presented to the inspectors. CC No XX and CC No YY were discussed. CCs were recorded department wise.

The SOP "Deviation" was discussed. Deviations were classified as:
- Minor
- Major
- Critical

The company claimed that till the date of inspection (18/7/2016) no deviations occurred and recorded.

Production related deviations were recorded in corresponding BMRs. The related SOPs were also discussed:
- "Internal investigation" – 5 Why' s were used for investigations
- "CAPA management"

CAPAs No XX and No CAPA YY were discussed.

13. Rejection and re-use of materials

Reprocessing / reworking

The SOP "Reprocessing and reworking" was discussed. According to the company explanation re-working was not done on site; however the SOP specified re-working procedure. The SOP was general and applicable to all products.

Recovery of materials and solvents, returns

The SOPs "Handling of mother liquors" and "Receipt of returned goods" were discussed. Returned goods were stored in locked rejected goods cage. According to the SOP returned goods could be sold (the same grade or different grade), reprocessed or reworked.

14. Complaints and recalls

The SOPs "Complaint" and "Product recall" were discussed. Head of compliance was responsible for dealing with complaints and recall. Recalls were classified as:
- Class I (immediate recall)
- Class II (within 1 to 2 days)
- Class III (within 3 days)
- Eternal

According to the SOP mock recall should be carried out once per year. Till the date of inspection (18/07/2016) mock recall was not executed. It was noted that mock recall was executed from the old site (local market); report was presented to the inspectors.

15. Contract manufacturers (including laboratories)

Production operations were not contracted out. Certain tests were contracted out to outside laboratories.

PART 3

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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 deficiencies listed in the Inspection Report, as well as corrective actions taken and planned:

- APIMF146 **Zinc Sulfate Monohydrate**

manufactured at Canton Laboratories Pvt. Ltd, located at Survey No. 350, Village Mujpur, Taluka Padra, Vadodara – 391440, Gujarat, 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 referenced in the inspection

1. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   http://www.who.int/medicines/publications/44threport/en/

2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical

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Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5
Short name: WHO TRS No. 961, Annex 5
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

6. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

7. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1
Short name: WHO TRS No. 961, 957), Annex 1
http://www.who.int/medicines/publications/44threport/en/

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6
Short name: WHO TRS No. 961, Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9
***Short name: WHO TRS No. 961, Annex* 9**
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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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

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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
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