World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Solara Active Pharma Sciences Limited
Corporate address of manufacturer	Solara Active Pharma Sciences Limited 2nd Floor, Administrative Block 27, Vandaloor kelambakkam Road Keelakottaiyur Village, Melakottaiyur Post. Chennai 600 127, Tamil Nadu, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Solara Active Pharma Sciences Limited A 1 /B SIPCOT Industrial Complex, Kudikadu Village, Cuddalore 607005, Tamil Nadu, India.
Synthetic unit /Block/ Workshop	Production Block IV
Inspection details	
Dates of inspection	23 – 27 January 2023
Type of inspection	Routine
Introduction	
Brief description of the manufacturing activities	Manufacturing, quality control and release of intermediates and APIs.
General information about the company and site	Pursuant to the strategic decision to combine the two companies, Shasun Pharmaceuticals Limited was merged with Strides Arcolab Limited by renaming the new combined entity as "Strides Shasun Limited". Further to that, based on the decision of the management the commodity API business was demerged from other business and a new entity was formed. The newly ventured entity was named as "Solara Active Pharma Sciences Limited" and came into effect from 1st April 2018 onwards. Solara has five API manufacturing facilities located at Cuddalore, Puducherry, Mangalore, Visakhapatnam and Ambernath, accredited with global regulatory approvals and one Intermediate

<table>
<tr><td></td><td>facility located at Mysore, and a dedicated R&D facility located at Chennai.

Major changes since WHO pre-inspection

1. Decommissioning of Production block I facility in 2017.
2. Commissioning of new water system -II (Ion Exchange).
3. The firm’s name has been changed from “Strides Shasun Limited” to “Solara Active Pharma Sciences Limited” since 1st April 2018.
4. Relocation of Microbiology lab opposite to Quality Control Building.
5. Change in Senior Leadership team</td></tr>
<tr><td>History</td><td>This was the third onsite inspection by WHO PQT of this site. The last onsite inspection by the PQT was performed in October 24-26, 2016.

According to the company’s declarations, the following authorities (last 5 years) have inspected the site:

<table>
<tr><th>Authority</th><th>Dates of inspection</th><th>Scope of inspection</th></tr>
<tr><td>EDQM & MHRA</td><td>09-11 January 2017</td><td>Facility</td></tr>
<tr><td>PMDA</td><td>07 – 09 March 2017</td><td>Production Block II & Packing Section III</td></tr>
<tr><td>USFDA</td><td>17 -21 April 2017</td><td>Facility</td></tr>
<tr><td>USFDA</td><td>01 - 05 July 2019</td><td>Facility</td></tr>
<tr><td>USFDA</td><td>02 - 07 March 2020</td><td>Facility</td></tr>
<tr><td>KFDA (Virtual)</td><td>26 – 28 September, 2022</td><td>Production Block VC & Packing Section XIV</td></tr>
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</td></tr>
<tr><td colspan="2">Brief report of inspection activities undertaken – Scope and limitations</td></tr>
<tr><td>Areas inspected</td><td>Pharmaceutical Quality System
Documentation
Facilities and Equipment (warehouses, tank farm, production blocks, laboratories)
Utilities
Production
Quality Control
Packaging and labelling
Product Release</td></tr>
</table>

Restrictions	Not applicable
Out of scope	APIs out of scope of prequalification
WHO APIs covered by the inspection	Cycloserine - WHOAPI-177
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
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
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
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
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
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

Part 2	**Summary of the findings and comments**

1. Quality management

Principle

Production and control operations were specified in written form and GMP requirements were essentially being met. Product and processes were monitored, and the results were reviewed as part of the approval process of batch release. Regular monitoring and reviews of the quality of pharmaceutical products were conducted according to documented schedules and procedures. A customized software was used for:

- Deviations
- Change Controls
- Complaints
- Corrective and Preventive Action (CAPA)
- Out of Specifications (OOS) and Out of Trend (OOT)
- Internal Audit (Self- Inspection)
- Standard Operating Procedures (SOPs in Track Wise Document Management System)
- Root Cause Investigation (RCI)

Data integrity

The data integrity policy and Data back-up and recovery management procedure were discussed. The document was applicable to all Solara employees. Training on fundamental data integrity principles was provided to all employees. The document explained ALCOA principles. Electronic data acquisition systems were configured, validated, and maintained. The data integrity system was audited by internal audits.

Functional Risk Assessment

All the different applications used on-site were validated. The functional risk assessment for selected applications was discussed.

Computer System Validation

The relevant validation master plan was reviewed. The VMP provided an overview of each process and described the validation approach, supporting validation rationale, and principles to maintain the systems in a validated state. Custom and configured software were requalified every 3 years whereas

infrastructure and non-configured software were requalified every 5 years. Periodic review reports for selected applications were reviewed.

Management review (MR)
The relevant procedure was reviewed. Participants of site meetings and quality forum were specified. Site Quality System Review and Quality Forum review agendas were also specified. Both the Site Quality System Review and Quality Forum Review meetings were conducted monthly. Minutes of the Site Quality System Review and Quality Forum Review were reviewed. The attendance lists were available. Top management was involved in the management review meetings.

Product Quality Review (PQR)
The relevant procedure for Product Quality Review was reviewed. PQR were conducted annually. PQRs were prepared for all commercialized batches of all APIs/ Intermediates manufactured in the previous year. PQR for Cycloserine (2021) was reviewed.

Quality Risk Management
The procedure for Quality risk management was reviewed. A Quality risk-based prioritization plan was created annually - first quarter of every calendar year by the Quality function to prioritize QRM initiatives for the year. Steps for RA were defined. Verification of QRM process, methodologies, and Risk Management methodology and reference tools were explained.

Deviations
The procedure for Deviation management was discussed. According to the SOP, the deviation owner shall perform immediate actions upon observation of the deviation. Actions that could be taken included but not limited to; segregation or containment, suspension / hold of operation, affixing of appropriate status labels, and performance of an initial impact assessment. The impact of the deviation on other lots / batches / products / materials / equipment / applications etc., was also assessed. All deviations were to be closed within 30 working days after reporting. Any deviation kept open beyond 30 working days were explained and justified in the deviation form.

Trending was performed by QA on monthly and yearly basis. Deviations were classified:
- Critical
- Major
- Minor

A number of deviation investigation reports were reviewed.

Corrective actions and preventive actions (CAPA)
The relevant procedure was reviewed. The procedure described actions initiated as part of the recommendations from QMS elements and subsequent investigations arising out of various quality management systems:
- Complaint Management
- OOS/OOT
- Recalls
- Deviations
- Regulatory inspections

- Process performance trends
- Product Quality Reviews
- Quality Risk Management
- Improvement Plans
- Quality System Review
- Returned Goods
- Validation/Qualification
- Customer Audit
- Internal Audit

CAPAs log for 2022 was available and several records were reviewed.

Change control (CC)
The procedure for Change management was reviewed. SOP was applicable to documents, processes, equipment, utilities or systems and new product introduction. Changes were categorised as: Permanent and Temporary.
A number of change controls were briefly discussed.

Complaints
SOP "Handling of customer complaints" was reviewed. SOP was applicable to customer complaints related to intermediates and APIs.
Complaints were received verbally or by written communication along with/without samples from:

- Agents
- Marketing representatives or representatives from any business region
- Customers
- Regulatory Agencies
- Employees

According to the SOP, closure of all complaints should be within 90 calendar days of log in of complaint or as agreed. Other timelines as preliminary report, follow-up final / report were specified. If required recall was considered as well as impact to other batches. Complaints were classified as: Critical, Major and Minor.
Trending was performed by QA on monthly and yearly basis. A complaint log was maintained.

A number of complaint investigation records were discussed.

Recalls
SOP "Product recall & market withdrawal" was reviewed. Recalls were classified as:

- Class I: initiated within 24 hours
- Class II: initiated within 48 hours
- Class III: initiated within 5 days
- Class IV: initiated within 14 days

Effectiveness of recall procedure was evaluated by Mock recall, which was performed once in 3 years.

Till the date of inspection, no recalls were executed. The report for last mock recall for export market was available.

Documentation
SOPs "Document management" and "Management of standard operating procedures" were reviewed. Document retention periods were specified. SOP explained creating, reviewing, approving, distributing, retrieving, and archiving) of SOPs. SOPs were managed electronically. SOPs were reviewed by the QA representative and approved by the Head/ Designee of QA and distributed by the Group QA representative. SOPs were reviewed mandatorily 3 years from the effective date of the SOP.

Internal Audit
SOP "Internal audit program" was reviewed. Corporate QA was responsible for scheduling, planning, preparation, co-ordination, and execution of internal audits. Auditor's selection criteria were specified. Deficiencies were classified as: Critical, Major and Minor. Internal audit plans for 2022 and 2023 were available. The list of qualified auditors was also available.

Vendor qualification
SOP "Vendor qualification" was reviewed. SOP was explained qualification of:
- Raw materials vendors
- Packaging materials vendors

The procedure described the process of identification, qualification, and evaluation of vendors. Manufacturing sites of API starting materials, advance intermediates and primary packing materials were audited (either onsite or remote desktop) once in 3 years.

Annual audit plan was available.

Non-conformances were classified:
- Critical non-conformance
- Major non-conformance
- Minor non-conformance

Product release
SOP "Product release" was reviewed. Upon completion of manufacturing process, production personnel sent Product Analysis Request (PAR) or in-process analysis request to QC to perform the sampling. BMRs/BPRs and analytical records were reviewed by QA. SAP system was used for batch release.

SOP "Management of specification, standard testing procedures, records of analysis and Certificate of Analysis" was also reviewed. COAs were prepared by the QC representative, reviewed by the QC supervisor/reviewer, and approved by the Head QC/designee. A Certificate of analysis for Cycloserine was verified and found satisfactory.

2. Personnel

SOP for "Training" was reviewed. SOP was applicable for permanent employees and service providers (contract employees). "Job Role Matrix" was prepared in accordance with the respective job descriptions. "Job Role Mapping Document" was based on the job description/role of employees and was used for new employee joining/role change.

SOPs "Technique evaluation of an analyst" and "Personnel" were also reviewed. The training schedules for 2022 and 2023 were available. Training records were maintained.

3. Production system

Production operations followed defined procedures. Significant deviations from the initial protocol were recorded and investigated, root causes were determined and CAPAs were implemented where necessary. Checks on yields and reconciliation of quantities were carried out. Access to production premises was restricted to authorized personnel. Sampling was performed by QC personnel.

Reprocessing

The SOP "Reprocessing" was reviewed. For batches that did not conform to established standards or specifications, a failure investigation was performed in accordance with the Out of specifications and relevant procedures. The QA head or designee assessed whether the proposed reprocess methods have any impact on Quality and any other related systems. The Executed Reprocess batch were subjected to stability studies. Manual register of reprocessed batches for 2022 was available.

Reworking

SOP "Reworking" was reviewed. Head QA or designee reviewed and approved the rework batch record. The rework batch details shall be monitored annually as part of Annual product review. Reworked batches were subjected to Stability testing.
The register of reworked batches for 2022 was checked – no batches reworked.

Blending of batches

SOP "Blending of APIs/intermediates/excipients" was reviewed. According to the SOP Out-of-specification batches should not be blended with other batches for the purpose of meeting specifications. Oldest input batch manufacturing date shall be assigned for blended batch manufacturing date. It was explained that blending was not applied for Cycloserine API.

Process validation

SOP "Process validation" was reviewed. SOP was applicable for process validation of both new as well as legacy products. Three process validation stages were explained:

- Stage 1 – Process Design:
- Stage 2 – Process Qualification:
- Stage 3 – Continued Process Verification:

According to the SOP: Continuous Process Verification shall be conducted annually.

Recovery of solvents
SOP "Procedure for recovered solvent and usage guidelines" was briefly reviewed. Recovered solvents were used in the same stage and same product.

Quality report for recovery of methylene dichloride (MDC) was reviewed.

BMR/BPR
BMRs and CoAs of selected batches of Cycloserine were reviewed.

4. Buildings and facilities
Inspectors visited production block IV, where Cycloserine API was manufactured and Packaging section V. In general, production premises were located, designed, constructed, adapted, and maintained to suit the operations to be carried out. Premises were cleaned and disinfected according to written procedures; records were maintained. In general production premises visited were seen to be maintained in good order.

SOP "Selection and evaluation of external service provider" was reviewed. SOP was applicable to external service providers (ESP) for activities such as: e.g., pest and rodent control, calibration, equipment/utility validation, analytical testing, transporters, and other miscellaneous services (like external record storage service). Quality agreements and audit reports of selected Contract Testing Laboratories were briefly reviewed.

Validation Master Plan
"Validation master plan for computerized system (VMP)" was reviewed. VMP explained the overall strategy applied to computerizes systems (CS) validation and how to maintain systems in validated state. VMP for CS was mandatory revised every 3 years.

SOP "Validation master plan (VMP)" was reviewed. VMP covered:
- Facilities
- Equipment & instruments
- Manufacturing Process/methods/system /cleaning methods
- Computer systems (e.g., Computer, Software, PLC's.)
- Utility (e.g., Water system, HVAC etc.)
- Analytical method
- Transportation
- Personnel
- Additional Validation / Qualification activity (e.g., Temperature mapping, miscellaneous etc.)

VMP specified re-qualification and re-validation requirements, periodic re-qualification, and annual validation/Qualification plan.

Cleaning Validation

SOP "Cleaning validation" was reviewed. In case of Nitrosamine Impurities presence in the Intermediate/ Active Pharmaceutical Ingredients, the respective cleaning process was evaluated to assess the potential carryover and removal of Nitrosamine Impurities residue in the Intermediate/ Active Pharmaceutical Ingredients for both dedicated and non-dedicated equipment based on the risk assessment.

Two types of cleaning procedures were applied:
- Cleaning during batch to batch:
- Cleaning during Campaign / Product changeover:

Matrix approach was used for cleaning validation. Validated excel sheets were used for MACO calculation. For calculation of MACO, following four criteria were considered and the most stringent was applicable for the cleaning validation:
- Acceptance criteria using health-based data
- Acceptance criteria based on Therapeutic Daily Dose
- Acceptance criteria based on LD50
- General Limit as acceptance criteria

Rise and swab samples were used. Periodic cleaning monitoring program (Cleaning Verification) was explained. Cleaning Verification shall be carried out once in a year according to the SOP.

Utilities

- HVAC system

Inspectors visited the HVAC system which supplied air to Packing section V where Cycloserine API was packed. In total there were 13 AHUs. The filter cascade was EU4→EU8→EU9. HEPA filters were terminally installed in the supply air system for the drying/sieving/milling/Packing rooms.

Environmental monitoring (EM) was performed was performed once in 3 months for total aerobic microbial counts (bacteria and fungi).

Equipment qualification

- Dispensing Booth

Report for the requalification of selected dispensing booth were reviewed.

- HVAC system

SOP "Performance qualification/re-qualification for HVAC systems" was reviewed. For performance evaluation of HVAC, the following tests were performed every year.

Protocol and Requalification Report of the AHUs in the Packaging section V was checked. The acceptable criteria was defined, and the all the tests met the set criteria.

- Incubators and other storage equipment

SOP "Qualification of laboratory incubators and other storage equipment" was reviewed. Distribution studies were performed for empty and loaded chamber (incubators). Temperature mapping study was performed as per the pre-approved protocol.

Initial PQ of walk-in stability chamber regular/standby compressor, storage conditions 25 ± 2 °C & 60 % ± 5% RH was checked. Re-calibration was performed annually. Calibration report for the in-built sensors was also checked.

Preventive Maintenance

Preventive maintenance and calibration schedules for the year 2022 and 2023 was available. The following preventive maintenance and calibration records of the following selected equipment were checked:

- Reactors
- Standard weights

Temperature mapping

SOP "Temperature mapping of room area" was reviewed. The SOP was applicable to various rooms/areas intended to use for storage of Products, Raw materials, Intermediates (e.g., RM storage area, Product quarantine area, Day store, Finished product store, etc.). The temperature mapping study report was available.

Utilities purified water (PW)

PW system was commissioned 2018 and Phase III validation was finalized in 2019. PW system: Source water →Multi grade filter →Ultra filtration→degassing→2RO→EDI→PW storage tank→2 distribution loops.

Online monitoring:

- Conductivity
- TOC
- UV intensity/hours
- Velocity - return

Spray balls were checked (PM) every 6 months, hydrophobic filters were changed every 6 months, integrity checks were performed before installation.

"Routine monitoring schedule for PW generation system for production block II, III, IIIA and IV" was checked. Alert and action limits were defined. PW monthly trends for two sampling points (return loops GSP 5 and GSP 7) were checked.

Laboratory premises

Laboratory areas were separated from production areas. Microbiology laboratory (MB) was located in a separate building in front of QCL. Inspectors visited QCL laboratory – stability room, reference standard room, wet chemistry, HPLC laboratory, sample preparation room, GSMS, UVVIS and FTIR rooms.

Microbiology laboratory was not visited, only schematic drawing was checked and explained. Work with master strains, sub-culturing and growth promotion tests were performed in biosafety cabinet, testing and media preparation was carried on in two separate RLAFs.

Laboratory equipment
Control, weighing, measuring, monitoring and test equipment were calibrated according to certified standards. Calibration records were maintained. Equipment usage logbooks were maintained. The calibration documentation for the following equipment were checked:

- HPLC
- UVVIS
- FTIR
- pH meter
- Analytical balances

5. Laboratory control system

Reserve samples
Reserved samples were stored in movable metal racks at room temperature of NMT 25 °C. The temperature was recorded manually once per day.

SOP "Management of reserve samples" was reviewed. The temperature and humidity of the storage area was recorded. Samples were retained for additional one year from the date of expiry/retest period of each product.

Reference standards
Reference standards were stored in temperature-controlled chambers. Temperature in chambers were recorded continuously and verified once per day online. Reference standards storage chambers and stability chambers were equipped with a sound alarm system.

SOP "Handling and maintenance of laboratory analytical standards" was reviewed. Standards were prepared for distribution under LAF or in a clean area to avoid contamination.

Out of Specifications
SOP "Handling of Out of Specification results" was reviewed. The Steps for identification of OOS, Phase I and Phase II investigations were explained.

Chromatographic practices
SOP "Good Chromatographic practices" was reviewed. Columns washing procedures and injection sequence were explained. Manual integration was not allowed.

Stability Monitoring
SOP "Stability management" was reviewed. Stability samples were analyzed as per monthly stability planner.

Stability summary reports for Cycloserine batches were checked.

Returned/Rejected finished products
SOP "Control, review and disposition of customer returned/rejected finished products" was reviewed. Initial assessment of returned products was performed by QA.

Analytical method validation
The "Analytical method validation" was reviewed.

6. Materials system
Inspectors visited following:
- Solvents tank farm.
- Finished products return/reject room.
- General store
- Liquid drum store
- Solid/liquid materials warehouse.
- Activated carbon storage
- Primary and secondary packaging materials storage room.

Incoming raw/packaging material
SOP "Pre inspection of incoming raw/packaging material" was reviewed. Pre-inspection was done following check list.

Sampling
SOPs "Sampling" and ''Pre inspection of incoming raw/packaging material'' was reviewed. The SOPs was applicable to raw materials, packaging materials, intermediates, excipients, and finished products. The sampling criteria was described. Raw Material Sampling checklist was used.

SOP "Control of raw materials at warehouse" was briefly reviewed.

7. Packaging and labelling system
SOP "Operation of quick response code application" was reviewed.

Procedure of generation of QR code was demonstrated.

SOP "Packaging of active pharmaceutical ingredients/dispatchable intermediates" was checked.

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, ***Solara Active Pharma Sciences Limited***, located at ***A 1 /B SIPCOT Industrial Complex, Kudikadu Village, Cuddalore 607005, Tamil Nadu, India*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines for APIs.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of GMP Guidelines referenced in the inspection report

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

2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-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/

3. 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

4. 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

5. 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

6. 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. 957, Annex 1
   http://www.who.int/medicines/publications/44threport/en/

7. 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 3.
   Short name: WHO TRS No. 957, Annex 3
   http://www.who.int/medicines/publications/44threport/en/

8. 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

9. 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

10. 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

11. 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

12. 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

13. 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/

14. 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/

15. 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

16. 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

17. 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

18. 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 Multisource guidance or ***WHO TRS No. 996, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

19. 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/

20. 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

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