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Prequalification Unit - Inspection Services
WHO PUBLIC INSPECTION REPORT
Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Solara Active Pharma Sciences LTD., Cuddalore
Corporate address of the manufacturer	**Solara Active Pharma Sciences Limited** Corporate Office- TICEL BIO PARK LTD. 6th floor. Module No. 601, 602, 603 Phase II - CSIR Road, Tharamani Chennai, Tamil Nadu – 600113, India Tel: + 91 44 4344 6700 Fax: + 91 44 4740 6190 E-mail: info@solara.co.in Web site: www.solara.co.in
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	A-1/B, Sipcot Industrial Complex, Kudikadu Village Tamil Nadu, Cuddalore 607 005; India D-U-N-S Number: 65-056-4045 GPS coordinates: Latitude: North - 11˚ 41.104' Longitude: East - 79˚ 45.308'
Unit /Block/ Workshop	Production Block IV and Packing Section -V
Inspection details	
Dates of inspection	11-13 December 2025
Type of inspection	Routine Inspection
Introduction	
Brief description of the manufacturing activities	Manufacturing activities encompassed the manufacturing, quality control, and release of intermediates and APIs. Active pharmaceutical ingredients for only human use were manufactured at this site. Other manufacturing activities, such as animal APIs, chemicals, drugs, and steroids, were not carried out at the Cuddalore site.
General information about the company and site	Initially, the formulation business of Strides and the API and formulation business of Shasun were merged in November 2015, resulting in the establishment of a combined formulation and API business under Strides Shasun. Subsequently, a demerger was implemented, whereby the formulation business remained with Strides, while the API business was separated.

<table>
<tr><td></td><td>In April 2018, the API business originating from Strides Shasun and the human API business of Sequent were merged. This merger resulted in the establishment of Solara as a pure-play API business. The manufacturing activities thereafter focused exclusively on the manufacture of active pharmaceutical ingredients for human use.

About the Site in Cuddalore:
The Cuddalore API manufacturing site was established in 1991. The site operated as a multi-product API manufacturing facility. Manufacturing activities were conducted within several independent production blocks with associated packing areas.

The facility was inspected and approved by the Directorate of Drugs Control, Tamil Nadu, for the manufacture of drug substances and was certified for compliance with cGMP requirements.</td></tr>
<tr><td>History</td><td>In the last five years, the site was inspected by the following authorities:
<table>
<tr><th>Name of the Authority</th><th>Dates of inspection</th><th>Scope of inspections (e.g., block, workshop, etc., inspected)</th></tr>
<tr><td>WHO-Geneva</td><td>21-25 June 2021</td><td>Desk Review assessment</td></tr>
<tr><td>KFDA (Virtual)</td><td>26-28 Sep 2022</td><td>Production block VC</td></tr>
<tr><td>WHO-Geneva</td><td>23-27 Jan 2023</td><td>Production block IV</td></tr>
<tr><td>EU GMP (SUKL-CZECH Republic and INFARMED -Portugal)</td><td>07-09 Feb 2023</td><td>Production block IV</td></tr>
<tr><td>USFDA</td><td>31 Jul - 04 Aug 2023</td><td>Production block III</td></tr>
</table></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, including warehouses, tank farm, production blocks, and laboratories
• Utilities, including HVAC and water generation systems
• Production
• Quality control laboratory
• Packaging and labelling
• Product release</td></tr>
<tr><td>Restrictions</td><td>Not applicable</td></tr>
<tr><td>Out of scope</td><td>APIs, not included within the WHO inspection scope.</td></tr>
<tr><td>WHO APIs (including</td><td>Cycloserine with WHO no. APIMF177</td></tr>
</table>

WHO API or APIMF numbers) covered by the inspection	
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
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	Nonconformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PPE	Personal protective equipment
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
RM	Raw material
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

A detailed presentation of the site was provided during the opening meeting.

A defined Quality Management System was operated by the manufacturer and covered all activities from raw material receipt to finished API. Oversight of the system was performed by Quality Assurance, and compliance with approved procedures was ensured. Quality records, including deviations, complaints, OOS/OOT results, investigations, change controls, and CAPA, were managed electronically through a dedicated software system, which enabled structured documentation, traceability, and follow-up of quality-related events.

A quality policy was established and implemented at the site. Solara Active Pharma Sciences was committed to the development, manufacture, and supply of active pharmaceutical ingredients and intermediates in compliance with applicable national and international regulatory requirements. The policy emphasized compliance, integrity, transparency, continuous improvement of the quality management system, personnel training, and maintenance of facilities in a compliant state. The quality policy was approved by senior management and was communicated within the organization.

A Quality Unit independent of production was in place and fulfilled both quality assurance and quality control responsibilities. The persons authorized to release intermediates and APIs were specified. The Quality Unit was involved in all quality-related matters and reviewed and approved all relevant quality-related documents. Quality-related activities were expected to be recorded at the time they were performed.

Materials were not used prior to the satisfactory completion of evaluation and release by the Quality Unit.

Procedures were in place to ensure that responsible management was notified in a timely manner of regulatory inspections, serious GMP deficiencies, product defects, and related actions.

The Quality Assurance System comprised core elements including deviation and change management, complaint handling, internal audits, document control, qualification and validation, and oversight of equipment, utilities, and processes, thereby ensuring that manufacturing operations remained in a controlled and compliant state.

Product Quality Review

Product Quality Reviews were prepared in accordance with the applicable SOP to verify the consistency of the manufacturing process and the overall product quality. As defined in the SOP, the review included:

- Critical in-process control data and critical API test results
- Batches that failed to meet established specifications
- Critical deviations or non-conformances and related investigations
- Changes made to processes or analytical methods
- Results from the stability monitoring programme
- Quality-related returns, rejections, complaints, and recalls
- CAPA and assessment of their effectiveness.

The results of these reviews were evaluated, and an assessment was made to determine whether corrective actions or revalidation were required. The reasons for such corrective actions were documented. The applicable corrective actions were completed in a timely and effective manner.

The Product Quality Review for Cycloserine, covering the period from 1 Jan to 31 Dec 2024 and effective 31 Mar 2025, was reviewed and discussed. An annual planner for 2025, effective 31 Dec 2024, was available.

Quality risk management

Quality risk management was performed in accordance with the respective SOP, which defined the requirements for the evaluation of risks to product or system quality and the identification of appropriate mitigation measures. In specific cases, detailed assessments using risk management tools, such as FMEA, were performed. ICH Q9 (R2) was considered during the updating of the SOP, which was in progress at the time of the inspection.

A quality risk management register was available and discussed.

Evaluation of nitrosamine impurities was performed in accordance with the applicable SOP. Consequently, a summary report on the evaluation of nitrosamine impurities in Cycloserine (API) was prepared, with reference to the respective QRM. The potential for nitrosamine formation in the Cycloserine API was identified, including NDEA (N-nitroso-diethyl-amine), NDPA (N-nitroso-diiso-propyl-amine), and NEIPA (N-ethyl-N-nitroso-2-propanamine). In the report, all parameters present in the manufacturing process were reviewed and evaluated, including KSM, raw materials, PW, process equipment, and the manufacturing environment. The report was dated 30 Dec 2022. Declarations from the relevant suppliers were provided and available. The LOD and LOQ were defined, and the respective analytical method was developed in accordance with applicable guidelines.

Management review

Procedures were established to ensure that responsible management was promptly informed of serious GMP deficiencies, regulatory inspections, product defects, complaints, recalls, and related actions. In addition, regular management reviews were performed to verify the site's performance and to assess the need for corrective actions or revalidation of any process. The outcomes of such reviews were evaluated, and any agreed corrective actions were required to be completed in a timely and effective manner.

Deviations & CAPA Handling

Deviation management was defined as the evaluation and documentation of departures from approved instructions or established standards. A deviation management procedure was established in accordance with the applicable SOP.

Root cause investigations for complaints, deviations, OOS/OOT events, and related issues were conducted in accordance with the respective SOP using defined tools and were documented in the dedicated software application. CAPAs were proposed based on the outcomes of investigations, were reviewed and approved by QA, and their implementation was tracked electronically. Any deadline extension required justification and QA approval. CAPAs arising from QRM or improvement initiatives did not require root cause analysis.

Randomly selected deviation investigation documentation was reviewed and discussed.

Product release

Finished API batches were tested by QC using approved procedures, and compliant batches were approved electronically. Batch certification was performed through the issuance of a CoA by duly authorized personnel.

Batch release was conducted in accordance with the SOPs for Product release, Material release in SAP, SAP Functional Operation Procedure (product transaction), and Review of analytical records.

The test results of the API were entered into SAP manually by QC. The QA review of the manufacturing and testing records was documented in a checklist, which served as evidence of batch release. Based on this checklist, QC modified the status of the API in SAP and generated the CoA.

Qualified QA personnel released batches for sale in accordance with customer orders, supported by an authorized personnel master list.

The job descriptions of the QA Group Leader (Compliance Reviewer) and the QC Group Leader In-Charge were available and reviewed to verify the inclusion of their responsibilities. Moreover, the batch release records for Cycloserine were reviewed and discussed.

2. Personnel

Manufacturing activities were supported by an adequate number of personnel across all relevant departments.

The plant operated on a 24-hour basis, seven days a week, with three shift operations and one general shift. The general shift working hours were from 09:30 to 18:00.

Personnel qualification

An adequate number of personnel, qualified through appropriate education, training, and/or experience, were available to perform and supervise the manufacture of intermediates and APIs. The responsibilities of all personnel engaged in the manufacture of intermediates and APIs were specified in their respective job descriptions.

Gowning training was discussed during the inspection. Personnel were provided with training on appropriate gowning practices relevant to their assigned activities. Records of the conducted training sessions were maintained and were available for review.

The observation related to the Training of personnel was adequately addressed in the respective CAPA plan.

Personnel hygiene

A uniform dress code and appropriate PPE were provided to ensure a safe working environment and to prevent contamination of intermediates, APIs, and test samples. Cleanroom entry and exit were controlled in accordance with the respective SOP, and were applicable to both employees and visitors. Personnel involved in cleanroom operations were trained on the relevant SOPs and received annual GMP training. Staff were trained to avoid direct contact with intermediates or APIs.

Personnel wore clean full-body coveralls for the manufacturing activities in which they were involved, and such clothing was changed when appropriate. Additional protective apparel, such as safety goggles, was worn when necessary to protect intermediates and APIs from contamination.

Smoking and tobacco use were prohibited on site, and eating, drinking, and food storage were restricted to designated areas in accordance with the SOP for Personnel, effective 30 Jun 2025. Personnel with infectious diseases or open lesions were not permitted to perform activities that could compromise API quality. Individuals showing signs of illness or lesions were excluded from operations where their condition could impact product quality or testing results.

3. Buildings and facilities

The site layout was designed to support controlled and orderly manufacturing operations. The facility comprised multiple dedicated production blocks, including Blocks II, III, IV, V, and VC, as well as a separate hydrogenation block. Designated areas were provided for warehouses, solvent storage yards, quality control laboratories, and a microbiology laboratory. Access to the site was controlled through a main gate, and internal roads facilitated defined movement of personnel and materials, supporting segregation of activities and minimizing the risk of cross-contamination.

Design and construction

The inspection team visited Block IV, including the primary packaging area, which was located within the sieving area. Primary packaging was performed immediately after completion of the sieving activity.

Buildings and facilities used in the manufacture of intermediates and APIs were appropriately located, designed, and constructed to facilitate cleaning, maintenance, and operational activities in accordance with the type and stage of manufacture. The facilities were designed to minimize the potential for contamination.

Defined areas and/or appropriate control systems were in place for the following activities:

- Receipt, identification, sampling, and quarantine of incoming materials pending release or rejection
- Quarantine of APIs prior to release or rejection
- Sampling of intermediates and APIs, which was performed in the production area
- Holding of rejected materials prior to further disposition (e.g., return, reprocessing, or destruction)
- Storage of released materials
- Production operations
- Packaging and labelling operations, which were performed in the production area
- Laboratory operations

Washing and toilet facilities were provided for personnel and were equipped with hot and cold water, as appropriate. These facilities were separate from, but easily accessible to, the manufacturing areas. Laboratory areas and operations were separated from production areas.
Written procedures were in place and were followed for the cleaning and maintenance of the facilities.

The observation related to the Design of the building was adequately addressed in the respective CAPA plan.

4. Process equipment

Design and construction

In general, equipment used in the manufacture of intermediates and APIs was of appropriate design, of adequate size, and suitably located for its intended use, as well as for cleaning, sanitization (where appropriate), and maintenance.

Equipment was constructed such that surfaces in contact with raw materials, intermediates, or APIs did not adversely affect the quality of intermediates or APIs beyond official or other established specifications. Production equipment was used only within its qualified operating range.

Equipment maintenance and cleaning

Control, weighing, measuring, monitoring, and test equipment critical to assuring the quality of intermediates and APIs were calibrated in accordance with written procedures and an established schedule. Schedules and procedures, including the assignment of responsibilities, were established

for the preventive maintenance of equipment. Preventive maintenance activities were managed through software system.

Written procedures were established for the cleaning of equipment and its subsequent release for use in the manufacture of intermediates and APIs. The cleaning procedures included sufficient detail to enable operators to clean each type of equipment in a reproducible and effective manner. Randomly selected SOPs, including the SOP for the cleaning procedure for process reactors and the SOP for the cleaning of centrifuges, were reviewed to verify that the following aspects were addressed:

- Assignment of responsibility for equipment cleaning
- Cleaning schedules, including, where appropriate, sanitization schedules
- Use of purified water for cleaning of Cycloserine equipment
- Establishment of the maximum time permitted between completion of processing and equipment cleaning, where applicable

During a discussion with QA, it was stated that the disassembly and reassembly of each item of equipment, to ensure appropriate cleaning, were requested from the service engineer in accordance with the applicable SOP.

Equipment and utensils were cleaned and stored in a manner that prevented contamination or carry-over of materials. Non-dedicated equipment was cleaned between the production of different materials to prevent cross-contamination. Acceptance criteria for residues, as well as the selection of cleaning procedures and cleaning agents, were defined and justified.

The cleanliness status of equipment and rooms was displayed at the locations where the equipment was installed. For the cleaning of equipment used for Cycloserine, only water was used, and no other solvent was applied, as the API showed good solubility in water.

The following documentation for the centrifuge, used at the final stage of production (IPA and ethanol washing and spin drying), was requested and reviewed:

- Qualification: The design specification and IQ, OQ, and PQ documentation were available.
- Maintenance: Preventive maintenance was managed in the dedicated software system according to an established schedule. Records of completion of the activity were documented in the software. A “Tasklist for Plant Maintenance” template was available and was completed for each scheduled activity. Maintenance executed on 29 Oct 2025 was available and reviewed.
- Cleaning and cleaning validation: The equipment cleaning record dated 5 Jan 2025 was available and was reviewed.

The selected documentation for the stainless-steel reactor, used for the final stage of production, was requested and reviewed. The requalification frequency was every five years.

The observation related to the Equipment maintenance and cleaning was adequately addressed in the respective CAPA plan.

5. Documentation and records

All documents related to the manufacture of intermediates or APIs were prepared, reviewed, approved, and distributed in accordance with the SOP for Management of SOP, effective 8 Jul 2024, and SOP for Control of Documents, effective 4 Oct 2024. Documents were maintained in paper and/or electronic form. The issuance process for paper documents was described in the respective SOP.

A procedure for document management and retention was established. Retention periods for the applicable documents were specified in Annexure 6 of the SOP. Electronic signatures were used and were required to be authenticated and secure in accordance with SOP for Digital Signature, effective 21 May 2024.

Approved Master labels were controlled and maintained within the software system. Master production instructions for each intermediate and API were prepared, dated, and signed by one person and were independently checked, dated, and signed by a person from the Quality Unit to ensure uniformity from batch to batch.

The master production instructions for Cycloserine were reviewed to verify that they included the following information:

- The name of the intermediate or API being manufactured
- A complete list of raw materials and intermediates, identified by names or codes sufficiently specific to identify any special quality characteristics
- An accurate statement of the quantity or ratio of each raw material or intermediate to be used, including the unit of measure; where quantities were not fixed, the calculation for each batch size or rate of production was included, and any justified quantity variations were documented
- The production location and the production equipment to be used
- Detailed production instructions, including:
  - The sequence of processing steps
  - The ranges of process parameters to be used
  - Sampling instructions and in-process controls, including acceptance criteria where applicable
  - Time limits for completion of individual processing steps and/or the overall process, where applicable, and expected yield ranges at appropriate stages or time points
  - Special notations and precautions to be followed, where applicable

Batch production records

Batch production records (BMR/BPR) were prepared for each intermediate and API and included complete information relating to the production and control of each batch. Prior to issuance, the batch production record was checked to confirm that it was the correct version and a legible and accurate reproduction of the approved master production instruction. Production of a new batch was initiated through a process order in the software.

The BMRs for Cycloserine were reviewed, including Stage I, Stage II, Stage III), and Stage IV.

Original data for in-process controls were maintained. Test data were complete and contemporaneous, and entries were signed and dated. The accuracy and completeness of the records were confirmed by a second person as an integrity check. These records were assigned a unique identification number and were dated and signed at the time of issuance. Documentation demonstrating completion of each significant step in the batch production records included the required information in accordance with the applicable SOP.

Review and approval of batch production and laboratory control records, including packaging and labelling, were performed in accordance with SOP, to determine compliance of the intermediate or API with established specifications prior to batch release or distribution.

Batch production and laboratory control records for critical process steps were reviewed and approved by the Quality Unit prior to release or distribution of an API batch. Deviations, investigations, and OOS reports were reviewed as part of the batch record review prior to batch release, in accordance with the applicable SOP.

6. Materials management

Manufacturing activities were performed in the production blocks using dispensed raw materials. Subsequent stages were labelled, sampled, analysed, and released by QC and QA in the software. Packing of intermediates and APIs was performed in suitable containers in accordance with the respective packing procedures. Finished products were packed and stored in cleanrooms meeting GMP Grade D (ISO Class 8) classification. Appropriate labelling of approved and rejected materials was performed, and the materials were stored in the designated areas.

Receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of materials were performed in accordance with the applicable SOPs, including Control of RMs at the warehouse, Control of PMs at the warehouse, Generation of the GRN in the software system, and Dispensing and issue of RM/PM.

Based on market requirements and customer sales orders, products were verified and released to customers in the software system in accordance with applicable regulatory procedures. Intermediates and APIs were stored under the required conditions.

A system was established for the evaluation of suppliers of critical materials. Materials were purchased against agreed specifications from suppliers approved by the Corporate Quality Unit. Changes to the source of supply for critical raw materials were managed in accordance with the change control procedure. Supplier approval included an evaluation that provided adequate evidence, including past quality history, that the supplier could consistently provide materials meeting established specifications.

The electronic records for material receipt, warehousing, status management, and dispensing of D-serine were reviewed and discussed.

Sampling and testing of incoming production materials

Upon receipt and before acceptance, each container, or grouping of containers, of materials was visually examined in accordance with the SOP for inspection of incoming raw materials and packaging materials. Receipt of materials was recorded in a pre-inspection checklist.

All incoming materials were sampled in accordance with the √n+1 plan. The supplier's CoA was accepted instead of performing certain tests only for highly toxic or hazardous materials.

Sampling of raw materials and finished products was performed by QC. In-process and intermediate stages were sampled by production personnel into dedicated containers by trained personnel. Sampling of RM/PM/API was controlled using a sampling checklist, which formed part of the analytical report.

Analytical test results for RMs were entered into the LIMS, which was interfaced with the applicable software system. The CoA was generated automatically in the respective software system in accordance with the SOPs for Review of analytical records, and Handling of sample management in the LIMS.

Samples were representative of the batch of material from which they were taken. Sampling methods for in-process materials, intermediates, and APIs were defined in the SOP and included:

- the number of containers to be sampled,
- which part of the container to sample, and
- the amount of material to be taken from each container.
- the number of containers to sample and the sample size were sufficient.

Storage

Warehouse and material management arrangements were in place for raw materials and packaging materials. Storage areas were segregated and controlled by material status (quarantine, approved, and rejected). Separate sampling and dispensing booths were available for solid and liquid raw materials. Solvents were stored in dedicated storage tanks and drums, and cold storage was available for temperature-sensitive materials. Packaging materials were stored in designated areas with segregation by status, and primary and secondary packaging materials were stored separately.

Materials were handled and stored in a manner that prevented degradation, contamination, and cross-contamination. Materials stored in fibre drums, bags, or boxes were kept off the floor and, where appropriate, suitably spaced to permit cleaning and inspection.
Materials were stored under the following conditions:

- Ambient temperature: 25–40 °C
- Controlled temperature: NMT 25 °C
- Cold storage: 2–8 °C

The layout of the RM warehouse was available.

7. Production and in-process controls

Acceptance criteria, as well as the type, extent, and criticality of in-process controls, were defined. Critical control points and control methods were documented in the BMR and approved by the Quality Unit.

In-process testing, results, and any process adjustments made within approved limits were documented in the batch records.

Production operation

Raw materials for the manufacturing of intermediates and APIs were weighed or measured under appropriate conditions that did not affect their suitability for use. Weighing and measuring devices were of suitable accuracy for the intended use.

Critical weighing, measuring, and subdividing operations were controlled. Prior to use, production personnel verified that the materials corresponded to those specified in the batch records for the intended intermediate or API. Actual yields were compared with expected yields at designated stages of the production process.

Where time limits were specified in the master production instructions, these limits were met to ensure the quality of intermediates and APIs. Intermediates held for further processing were stored under appropriate conditions to ensure their suitability for use.

The raw material and intermediate warehouse, as well as the finished API and intermediate warehouse, were visited on Day 2 and were found to be appropriate. The finished API warehouse used for Cycloserine was designed as a walk-in chamber maintained at 2–8 °C.

Vendor management

The Corporate SCM (Supply Chain Management) was responsible for the initiation of qualification and Corporate Quality unit was responsible for the approval of new vendors based on the sample test results of three batches, completion of the vendor questionnaire, and test result of first commercial lot, in accordance with the respective SOP. A site audit was required within one year of approval.

Regular vendor requalification was performed at three-year intervals. The evaluation records and the technical agreement for the new supplier of D-serine were reviewed and discussed.

Blending batches of intermediates or APIs

Blending was not applicable for this production.

8. Packaging and identification labelling of APIs and intermediates

General:

Packaging and labelling materials conformed to established specifications. Materials that did not comply with these specifications were rejected to prevent their use in operations for which they were unsuitable. This was verified during the review of the OOS investigation.

Packaging materials

For primary and secondary packaging, single-use PE bags, metal drums, and HDPE drums were used. These containers provided adequate protection against deterioration or contamination of intermediates or APIs during transportation and under the recommended storage conditions.

Packaging and Labelling Operations

SOP for Packaging of API and Dispatchable Intermediates ensured that the correct packaging materials and labels were used. Labelling operations were designed to prevent mix-ups and were physically separated from operations involving other intermediates or APIs. Labels applied to containers of intermediates or APIs included the name, identifying code, batch number, storage conditions, and expiry date.

Packaging and labelling facilities were inspected immediately prior to use to ensure that all materials not required for the next packaging operation were removed. This examination was documented in the batch production records and in the facility log.

Packaged and labelled intermediates or APIs were examined to ensure that all containers and packages within the batch bore the correct labels. This examination formed part of the packaging operation, and the results were recorded in the batch production or control records.

API containers transported outside the manufacturer's control were sealed in a manner that enabled the recipient to detect potential tampering in the event that a seal was breached or missing, in accordance with SOP for Control of Sealing Material Used for Packing. A temperature recording device was placed in the shipment, under the lid, in accordance with the applicable technical agreement with the customer.

The observation related to the Packaging and labelling was adequately addressed in the respective CAPA plan.

9. Storage and distribution

Refer to Section 6 for Storge.

10. Laboratory controls

The Quality Unit had adequate laboratory facilities. The respective SOP defined the procedures for sampling of raw materials, packaging materials, excipients, intermediates, and finished products. This SOP also applied to all excipients and finished products manufactured at the site.

Specifications, sampling plans, and test procedures were established to ensure compliance with defined quality and purity standards. The specifications included controls for impurities.

Reagents and standard solutions were prepared and labelled. The storage and records of reference standards used for verification of in-house working standards were reviewed and discussed. The use of reference standards was managed through the designated software system. The Cycloserine reference standard was supplied by the supplier through Strides Pharma.

Certificates of analysis were issued for each batch of intermediate and API.

Sample receiving and distribution

Three types of samples were handled at the site:

- Finished product samples: Samples taken from finished product batches were collected by QC personnel based on requests from the production unit. The samples were transferred to the laboratory for distribution, retention, and allocation to analysts in accordance with an approved competency list. Cycloserine samples were stored in a dedicated stability chamber with controlled access at 2–8 °C, using the same packaging as that intended for marketing.
- In-process samples: In-process samples were transferred to the QC laboratory through a designated pass-through window.
- Samples used for cleaning validation: Cleaning samples were transferred to the QC laboratory through a designated pass-through window.

Testing of starting materials, intermediates and APIs

For each batch of intermediate and API, appropriate laboratory tests were performed to determine compliance with established specifications.

Samples were analyzed in accordance with their respective STPs (standard test procedures). The analytical report for cleaning samples, conducted in accordance with the applicable STP for the Reactor and the Centrifuge used for Cycloserine, was reviewed, and the corresponding raw data were verified on the HPLC used. The analysis was performed after the production of Venlafaxine and before the subsequent production of Cycloserine.

An impurity profile was established for each API, describing identified and unidentified impurities present in a typical batch produced by a defined and controlled production process. The impurity profile included:

- The identity or qualitative analytical designation (e.g., retention time)
- The observed range of each impurity
- The classification of each identified impurity (e.g., inorganic, organic, or solvent)

The impurity profile was reviewed on an annual basis.

OOS management

Out-of-specification results were investigated in accordance with SOP for Handling of Out-of-Specification Results, effective 28 Mar 2025. The procedure applied to analytical results falling outside established specifications or acceptance criteria for raw materials, packaging materials, intermediates, recovered solvents, semi-finished products, and finished products. The procedure did not apply to in-process results, data generated during product development, trial batches, monograph evaluations, photostability studies, or vendor evaluation samples. It was applicable to OOS results related to stability testing, environmental and water monitoring, microbiological testing, physical parameters of products, packaging materials, water samples, hold time studies, reserve samples, and testing performed by contract laboratories.

Laboratory controls were documented in real time. Any deviations were documented and explained. OOS investigations were managed in the software and the corresponding reports were retained in the system. In addition, records of analyses, reports, and OOS investigations were

maintained as paper records issued through the electronic DMS in accordance with SOP for operation of the the application.

Randomly selected OOS investigation records from the OOS register were selected to be reviewed.

Retention samples

Reserve samples of Cycloserine were retained for the purpose of potential future evaluation of API batch quality.

Samples of each API batch were retained for one year after the expiry date assigned by the manufacturer.

Reserve samples were stored in the same packaging system as the API. Sufficient quantities were retained to allow at least two full analyses to be performed.

During the inspection, it was emphasized that, following retrieval, samples should be returned to their designated storage locations and maintained under the required storage conditions for the respective sample without undue delay, immediately after completion of the intended activity, in order to preserve sample integrity.

Stability study

SOP for Stability Management, effective 27 Nov 2025, described the stability management system. The procedure covered the selection of batches, sampling, receipt, storage, and initiation of studies to demonstrate or support the stability of drug substances, as well as the hold times for intermediates and in-process samples used to assign retest or expiry periods.

A documented and ongoing stability testing programme was in place to monitor the stability characteristics of APIs. The results were used to confirm appropriate storage conditions and assigned retest or expiry dates.

Selected stability-related documents were reviewed.

Hold time studies were performed in accordance with the applicable SOP. Hold time studies were conducted for Cycloserine Stage I, Stage II, and Stage III, with defined hold times of six months, three months, and 24 hours, respectively, following a recent change to the hold time study.

The report for the dirty equipment hold time study for Cycloserine (API) manufacturing equipment was available and reviewed. The report provided documented evidence supporting the dirty hold time for equipment used in the manufacture of Cycloserine (API) in Packing Section V. The report included a list of the equipment evaluated, along with the applicable specifications and acceptable ranges. The dirty equipment hold time was established as 24 hours (one day).

Microbiology laboratory

The Microbiology Laboratory was located on the 2nd floor of the Administrative Building. The laboratory performed sampling for microbiological testing, testing of APIs (not applicable to the inspected Cycloserine), purified water testing, environmental monitoring testing, and monthly trend analysis.

The laboratory areas were controlled and qualified as ISO Class 8 and ISO Class 7, as applicable. The main facilities included a media preparation room (also used for receipt of samples), an autoclave room, LAF Rooms I and II, an incubation room, and a washing and decontamination room.

Test records for TYMC and pathogens related to the most recent purified water sample (sampling point SPE-21), together with associated documentation, were reviewed and discussed. These included the incoming sample register (paper logbook), raw data sheets, media preparation records, incubator logbooks, media/BET receipt checklists, SOP for Monitoring of Water for Microbial Quality, dated 13 Sep 2024, and the operation SOPs and requalification records for the decontamination autoclave.

Instrument

Analytical balances were verified daily.

There were stability chambers, which were monitored through software application. The software was randomly verified for the temperature monitoring, alarm logs, and event records for the last month (11 Nov – 12 December 2025).

HPLC and GC were associated with a chromatography software application and connected to the server. Another software used for the UV spectrophotometer was also connected to the server.

A documented backup flowchart demonstrated that all computers running GMP-relevant software applications were connected to the central server. Data backups were performed in accordance with the defined backup strategy, including regular backups to tape media. Copies of the annual backup tapes were stored at an off-site location to ensure data security and business continuity.

Temperature mapping for the stability chamber was reviewed. The initial qualification was performed in 2021. A service report was issued. Calibration and validation activities were completed, and the identified hot spot was indicated on the respective document.

The observation related to the QCL was adequately addressed in the respective CAPA plan.

11. Validation

Validation documentation

The Validation Master Plan (VMP) described the planned sequence of validation activities to ensure that manufacturing and research facilities, equipment, instruments, utilities, and systems used for the manufacture, processing, packing, and storage of drug substances and intermediates were validated and maintained in a validated state. The VMP established standardized validation

practices across facilities, supported harmonization of validation activities, and facilitated the ongoing improvement of validation policies and procedures.

Computerized systems that could impact product quality, manufacturing processes, or testing activities were validated in accordance with the Computer System Validation Master Plan. The approach and methodology used to execute the various aspects of the computerized system validation programme were defined and implemented through the VMP-CS.

An annual requalification planner was in place to provide an overview of all equipment subject to requalification or revalidation. The planner included information on the last qualification performed, the defined frequency, and the next scheduled qualification date. The planner was reviewed and discussed during the inspection.

Computerized system validation

GMP-related computerized systems were validated through appropriate qualification of hardware and software to ensure their suitability for the assigned tasks, in accordance with SOP for Validation Master Plan for Computerized Systems, effective 26 Sep 2025. The validation lifecycle included the retirement phase.

The site operated an integrated inventory of GMP-relevant computerized systems supporting the electronic Quality Management System. Quality events and QMS processes were managed through the dedicated software. Material management and batch-related transactions were handled via the software. Laboratory testing and release activities were supported by LIMS, with an additional LIMS module under implementation. Document management was performed using the respective software. Technical training records and statistical data analysis were supported through the designated software systems.

A periodic requalification plan for computerized systems was available covering a period of time. The Periodic Requalification Plan (PRP) was intended to identify and schedule IT systems for periodic review to ensure continued compliance with regulatory requirements and fitness for intended use. GxP systems were required to be reviewed at defined frequencies based on system category, starting from the date of release for routine use. The PRP was prepared on a site-wise basis, including corporate systems. The periodic requalification planner was reviewed annually and updated as required.

A summary of the current year's PRP was prepared in January of the subsequent year to support the development of the plan for the next calendar year. Any deviations from the approved schedule were required to be justified and managed through the QMS, and changes to the approved planner were incorporated into the subsequent PRP revision. The approved PRP was maintained by QA, with controlled copies issued to the CSV function for execution. Periodic requalification activities were scheduled and performed by the CSV department.

Sufficient controls were implemented to prevent unauthorized access to, or modification of, data and to ensure data completeness. Any changes to data were required to be traceable through the audit trail, including the original entry, the identity of the individual making the change, and the

date of the change. Administration and user access control for GxP computerized systems were managed in accordance with the applicable SOP.

SOP for Review of Audit Trail, effective 30 Sep 2025, was established to define the procedure for review of audit trails in analytical software used in QC. The SOP was applicable to both chromatographic and non-chromatographic systems.

Written procedures were established for the operation, maintenance, and change control of computerized systems. All changes were required to be formally authorized, documented, tested, and recorded to demonstrate that the systems remained validated. SOP for Management of the Chromatography Data, effective 04 Dec 2025, was provided and reviewed.

Where system breakdowns or failures could result in permanent loss of records, an appropriate backup system was in place. Measures to ensure data protection for all computerized systems were established and implemented in accordance with SOP for Data Backup and Recovery Management, effective 17 Sep 2025. Processes were in place to verify that electronic records remained readily retrievable. The recovery test plan calendar was provided and was available for review. Evidence of successful data restoration performed on 31 Oct 2025 was reviewed.

Process validation documentation

The validation policy followed a lifecycle approach comprising Stage 1 (Process Design), Stage 2 (Process Qualification), and Stage 3 (Continued Process Verification). Process qualification was primarily prospective and was conducted using three consecutive batches. Concurrent validation was permitted only in exceptional cases, such as urgent market demand. Validation batches were permitted to be marketed only after approval of the final, or at least an interim, validation report, in accordance with a written agreement with the customer.

The most recent process performance qualification records (protocol and report) and the Continued Process Verification report for the Cycloserine API were reviewed and discussed.

Equipment qualification

HVAC and Environmental monitoring

The controlled manufacturing areas were supplied by 13 air handling units (AHUs). The performance of the HVAC systems was routinely verified through requalification activities and environmental monitoring, in accordance with established procedures for HVAC qualification and air sampling in controlled areas.

Annual requalification activities covered critical parameters including filter integrity, airflow velocity, air change rates, non-viable airborne particle counts, and, on a biennial basis, recovery testing and airflow visualization. The most recent requalification results and microbiological monitoring data for the sieving, milling, and packing room, which was served by AHU-1, were reviewed and discussed.

The requalification was performed in accordance with an approved protocol, and the report was provided following the installation of a new door in the changing area, renewal of the epoxy flooring, and as part of the routine annual requalification programme.

Operation and maintenance of the AHUs, including differential pressure monitoring and filter cleaning, were managed in accordance with the applicable SOPs.

Autoclave

Two autoclaves were operated in the microbiology laboratory: one dedicated to decontamination and one used for the sterilization of media and utensils. For decontamination activities, an overkill approach was applied at 121 °C for 60 minutes.

Operation and performance checks of the autoclaves were conducted in accordance with the applicable SOP. The autoclaves were subject to annual requalification. The most recent requalification records for the decontamination autoclave were reviewed and discussed.

The observation related to the Equipment qualification was adequately addressed in the respective CAPA plan.

Purified Water System

The site operated a qualified purified water system comprising bore-well feed, softening, reverse osmosis, and EDI units, supplying water through a closed-loop recirculation system. Purified water was stored in stainless steel tanks under continuous circulation. Routine chemical and microbiological monitoring was performed in accordance with pharmacopoeial requirements, and periodic sanitization was carried out using approved chemical and thermal methods. The system supplied purified water for API and intermediate manufacturing.

Purified water specifications complied with the applicable requirements. During Phase III qualification (2018–2019), sampling points and monitoring frequencies were defined. Routine monitoring was performed in accordance with the documentation for the generation system and for the distribution system. Requalification of the purified water system was conducted in accordance with the respective protocol. The layout of the purified water generation and distribution system was provided in Annexure 13 of the Site Master File.

Two separate purified water distribution loops were in operation at the facility. One loop supplied Blocks II and III, while a second loop supplied Block IV. These blocks were the only areas utilizing this purified water system. Blocks V and VC were supplied by a different water system and were not involved in the manufacture of Cycloserine.

Requalification of the purified water generation and distribution system supplying Production Blocks II, III, IIIA, and IV was replaced by an annual trend review summary report for physicochemical and microbiological monitoring for the year 2024. This approach was justified by the absence of deficient events, OOS results, or adverse trends. The annual trend review report was available and reviewed during the inspection.

The logbook for the RO-II and EDI systems was reviewed. The logbook recorded operational parameters for the cartridge filter, RO-II, EDI-I, EDI-II, and EDI permeate, including inlet pressure, feed pH, and conductivity. Entries were recorded every two hours by the respective shift personnel.

Filter replacements and any relevant observations or remarks were also documented in the same logbook.

Nitrogen system - Compressed air system

Standard procedures were in place governing the operation and maintenance of the boiler, compressed air, and nitrogen systems. These systems were qualified on an annual basis, with daily monitoring of critical parameters including pressure, flow, oxygen content, and dew point. Personnel involved in operation and maintenance were trained in accordance with the applicable SOPs. Periodic microbiological monitoring of compressed air and nitrogen was performed to detect potential contamination. System layouts were provided in Annexure 14 of the Site Master File.

Cleaning validation

Cleaning procedures were validated with emphasis on process steps where the risk of contamination or carry-over could have the greatest impact on API quality. The validation approach reflected actual equipment usage. Where multiple APIs or intermediates were manufactured using the same equipment, a representative substance was selected based on factors such as solubility, cleaning difficulty, and established residue limits.

The cleaning validation protocol defined the equipment to be cleaned, applicable cleaning procedures and materials, acceptable residue limits, parameters to be monitored, analytical methods, sample types, and sampling and collection procedures. Sampling methods included swab sampling and, where swabbing was not feasible due to inaccessible or complex equipment surfaces, rinse sampling was employed.

Cleaning procedures were subject to periodic monitoring at defined intervals following validation, to ensure their continued effectiveness. Equipment cleanliness was verified through a combination of analytical testing and visual inspection.

Selected documentation was reviewed and discussed during the inspection.

Validation of Analytical Methods

SOP for Analytical Method Validation, effective 4 Nov 2024, was reviewed. The analytical method validation protocol for nitrosamine impurities in Cycloserine using GC-MS/MS and the corresponding validation report, approved on 1 Aug 2022, were discussed.

Depending on the capacity of the QC laboratory, development and validation of analytical methods were outsourced. Validated methods were subsequently verified by the QC laboratory, or a formal method transfer was performed, depending on the product. For this purpose, three external laboratories were used.

12. Change control

A change management system was established in accordance. The procedure defined the process for evaluation, approval, and implementation of all changes that could impact the production and control of intermediates or APIs, including permanent and temporary changes to documents, processes, equipment, facilities, and related systems.

The SOP covered the identification, documentation, review, and approval of changes related to raw materials, specifications, analytical methods, facilities, support systems, equipment (including computer hardware), processing steps, labelling and packaging materials, and computer software.

Change requests were recorded and managed through the application. Change control records in the system from February 2023 onwards were reviewed and discussed. A number of change controls were present in the system. Open change requests were within their respective approved timelines. None of the open change requests were related to Cycloserine production. The only change identified as related to Cycloserine production concerned a change in management.

Randomly selected change control requests were reviewed.

Proposals for GMP-relevant changes were drafted, reviewed, and approved by QA following evaluation of their potential impact on the quality of intermediates or APIs. A classification procedure was applied to determine the required level of testing, validation, and documentation based on the nature, extent, and potential impact of the change. All affected documents were revised during implementation. Following implementation, the effectiveness of each change was evaluated.

13. Rejection and re-use of materials

Rejection

Rejection procedures were described in the SOP for batch release; reference was made to the respective section.

Reprocessing

An SOP for reprocessing was in place; however, no reprocessing activities had been performed for Cycloserine supplied to the WHO market.

Reworking was not applicable at this site.

Recovery of materials and solvents

Recovered solvents were reused in the same manufacturing processes in accordance with established procedures to ensure compliance with applicable quality standards prior to reuse or commingling with other approved materials. All related activities were documented in the respective batch manufacturing records.

Recovered solvents were used only after appropriate testing had confirmed their suitability for the intended manufacturing processes. The use of recovered solvents was adequately documented.

Returns

Refer to section “Storage.”

14. Complaints and recalls

All quality-related complaints, whether received orally or in writing, were recorded and investigated in accordance with SOP for Handling of Customer Complaints, effective 23 Oct 2025.

Complaint records included the name and address of the complainant, contact details of the individual submitting the complaint, the nature of the complaint (including API name and batch number), and the date of receipt. Records also documented initial and follow-up actions taken, including dates and responsible persons, the response provided to the complainant with the response date, and the final decision regarding the affected intermediate or API batch or lot. Complaint records were retained to allow evaluation of trends, frequency, and severity, and to determine the need for additional corrective actions.

SOP for Product Recall, effective 18 Oct 2024, was established to define the circumstances under which a recall of an intermediate or API should be considered. The procedure specified responsibilities for evaluation of information, initiation of a recall, notification of relevant individuals and authorities, and handling of recalled materials. In serious or potentially life-threatening situations, local, national, and/or international authorities were to be informed, and their guidance sought. No product recalls have been initiated to date of inspection.

A procedure was in place to conduct mock recalls in order to create awareness among personnel and to verify the effectiveness of the recall system. QA performed mock recalls once every three years, irrespective of market, to assess the adequacy of the recall procedure. The mock recall protocol, together with the corresponding report, was reviewed.

15. Contract manufacturers (including laboratories)

No contract laboratory was used for the testing of Cycloserine. One contract manufacturer was planned for Cycloserine Stage I, and this manufacturer had already been approved.

Contract manufacturers were evaluated by the Corporate Quality Unit to ensure technical competence and compliance with GMP requirements. A written and approved quality agreement was in place between the contract giver and the contract acceptor, clearly defining the GMP responsibilities and quality requirements of each party. The agreement also permitted the contract giver to audit the contract acceptor's facilities to verify ongoing GMP compliance.

Miscellaneous	
Samples taken	Not applicable
Assessment of the site master file	Site Master File was provided and reviewed.
Annexes attached	Not applicable

Part 3	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 LTD., Cuddalore***, located at ***A-1/B, Sipcot Industrial Complex, Kudikadu Village, Tamil Nadu, Cuddalore, 607 005; India*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

The deficiencies observed during the inspection, as listed in the full report, were addressed by the manufacturer to a satisfactory level before 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 GMP for APIs or WHO TRS No. 957, Annex 2***
   http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

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

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

5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

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

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

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

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

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

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

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3.
Short name: WHO TRS No. 943, Annex 3
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. ***Short name: WHO TRS No. 981, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3. ***Short name: WHO TRS No. 981, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

17. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
Short name: WHO GDRMP guidance or WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

22. WHO general guidance on variations to multisource pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report. Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO Multisource guidance or WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
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24. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1015), Annex 3.
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https://www.who.int/publications-detail/978-92-4-000182-4

25. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
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26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
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