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Prequalification Unit - Inspection Services
WHO PUBLIC INSPECTION REPORT
Finished Pharmaceutical Product (FPP) Manufacturer
WHOPIR

Part 1	**General information**
Manufacturers details	
Name of the manufacturer	Strides Pharma Science Limited (Puducherry)
Corporate address of the manufacturer	Strides House Bilekahalli, Bannerghatta Road Bangalore – 560076 India
Inspected site	
Name and address of the inspected manufacturing site	Strides Pharma Science Limited RS. No. 31, 32, and 33, PIMS Road, Periyakalapet Puducherry 605014 India D-U-N-S Number: 871402375 GPS coordinates: Latitude North 12.039649 Longitude East 79.855279
Unit/block/ workshop number	Formulation Unit, Puducherry, India Manufacturing [Pilot and commercial area]
Inspection details	
Dates of inspection	15 – 18 December 2025
Type of inspection	Routine inspection
Introduction	
Brief description of the manufacturing activities	The following activities were carried out at the site for Oral Solid Dosage Forms (OSDF), such as tablets and capsules: • Warehousing • Manufacturing (tablets and capsules) • Packaging (bulk, bottle, and blister packaging) • Testing (quality control) and release The facility did not manufacture products falling under the following categories: • Beta-lactam antibiotic products • Cytotoxic products • Steroids and sex hormone products Other than human solid oral drug products, no veterinary or poultry products were manufactured at this site.

<table>
<tr><td>General information about the company and site</td><td>The Puducherry site was established in 2005 under the name Shasun. Following a corporate merger with Strides Arcolab Limited in 2015, the entity operated as Strides Shasun Limited. Subsequently, in 2018, the name of the drug product manufacturing facility was changed to Strides Pharma Science Limited, under which the site continued its operations. The corporate office is located in Bangalore.

The company had seven manufacturing facilities spread across four continents. The company had R&D infrastructure in India with global filing capabilities. Strides was involved in site transfer and the manufacture of a wide range of pharmaceutical products.

<u>Puducherry site:</u>
The plant was spread over a total land area of about 10.86 acres. The production of Oral Solid Dosage Forms (tablets and capsules) commenced in the year 2005. The facility was used to manufacture and export pharmaceutical oral solid dosage forms as licensed by the state drug licensing authorities.

The manufacturing blocks were independent, with separate personnel entry, and were connected to each other for material movement. The Drugs Control Authority of the State of Puducherry approved the manufacturing site.</td></tr>
<tr><td>History of Regulatory Inspections</td><td>In the last five years, the site has been 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>OGYEI, Hungary</td><td>April 26 to 28, 2021</td><td>OSDF [Tablets and capsules]
Bulk, Bottle, and Blister Packaging</td></tr>
<tr><td>CDSCO, India</td><td>February 10 & 11, 2022</td><td>COPP grant</td></tr>
<tr><td>CDSCO, India</td><td>October 17, 2022</td><td>COPP grant (re-inspection)</td></tr>
<tr><td>WHO, Geneva</td><td>January 16 to 20, 2023</td><td>OSDF [Tablets and capsules]
Bulk, Bottle and Blister Packaging</td></tr>
<tr><td>USFDA</td><td>February 20 to 24, 2023</td><td>OSDF [Tablets and capsules]
Bulk and Bottle Packaging</td></tr>
<tr><td>Chief Pharmaceutical Inspectorate, Poland</td><td>April 8 to 11, 2024</td><td>OSDF [Tablets]
Bulk Packaging</td></tr>
<tr><td>CDSCO, India</td><td>September 23, 2024</td><td>COPP grant</td></tr>
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	Danish Medicines Agency (DKMA), Denmark	November 12 to 15, 2024	OSDF [Capsules] Bottle and Blister Packaging
	Botswana Medicines Regulatory Authority (BoMRA)	November 25 to 26, 2024	OSDF [Capsules] Blister Packaging
	CDSCO, India	February 13 to 14, 2025	GMP revalidation
	National Centre for Public Health and Pharmacy (NNGYK), Hungary	August 25 to 29, 2025	Routine GMP for OSDF [Tablets and capsules] Bottle and Blister Packaging

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Documents reviewed: • Quality management, and related activities • Personnel • Buildings and facilities • Sanitation and hygiene • Documentation and records • Materials management • Process equipment and utilities • Qualification and validation • Change control • BMR & BPR • Storage and distribution • Laboratory controls • Complaints and recall documentation Site areas visited: • General production • Warehouses • QC laboratory, including Physical, chemical, and microbiological • Water generation system utilities • HVAC system utilities
Restrictions	A detailed site presentation was provided at the opening meeting. It was noted that no products within the scope of the inspection had been manufactured since the last inspection and that there were no plans to manufacture any of these products. The inspection was therefore restricted to the assessment of the site as a backup manufacturing site for the respective WHO products. The company intended to retain the prequalification status for this purpose. TLD was manufactured at the Bangalore site, while Cycloserine was intended to be manufactured only at the Puducherry site.
Out of scope	Products other than, and areas not relevant to, the WHO-prequalified products listed below.

WHO product numbers covered by the inspection	**WHO application no. TB416** Cycloserine capsules, hard 250 mg **WHO application no. HA729** Dolutegravir (sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
GPT	Growth promotion test
HEPA	High-efficiency particulate air
HPLC	High-performance liquid chromatography
HVAC	Heating, ventilation, and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media Fill Test
MR	Management review
NC	Nonconformity
NCA	National control authority
NCL	National control laboratory
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
RCI	Root cause investigation
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
TLD	Tenofovir, Lamivudine, Dolutegravir
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

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

1. **Pharmaceutical quality system**

The site operated an integrated Quality Management System that covered both Quality Assurance and Quality Control. Quality Assurance oversaw core GMP activities, including documentation control, validation and qualification, product quality review, change control and deviation handling, management of complaints and recalls, CAPA, training, internal audits, stability study management, batch record review, release or rejection of raw materials, packaging materials and finished products, line clearance, artwork review, exhibit batches, risk management, and dispatch.

Quality Control was organized into Chemical and Instrumental Analysis, Microbiological Analysis, and Stability Testing. QC activities included testing of raw materials, packaging materials, intermediates, and finished products, as well as analysis of validation samples. Environmental monitoring, bioburden testing, microbial assays, and water analysis were carried out in the microbiology laboratory. The stability unit managed the testing and evaluation of stability samples.

In-process monitoring was in place to verify manufacturing steps and included in-process testing, approvals, and sampling of semi-finished and finished products.

The site used several electronic systems to manage key QMS activities.

LIMS handled analytical documentation for raw materials, packaging materials, intermediates, and finished products, as well as sample and reagent management, calibration, stability activities, and preparation of electronic raw data sheets. It was also used for stability protocols, planning, batch placement, and retrieval of time-point samples.

Supply chain monitoring was performed for the transportation of finished goods, which was validated before the first shipment. The validation covered both summer and winter conditions and was conducted using two sets of three batches. In accordance with the approved protocol and supporting records, transport validation and routine monitoring were defined in the applicable SOP.

Management Review
Periodic management reviews of the PQS operation were conducted, involving senior management, to identify opportunities for continual improvement of products, processes, and the system. Management reviews were conducted monthly in accordance with the SOP for Quality System Review, effective 31 March 2023. The most recent management review meeting minutes were available and were reviewed.

Handling of deviations & CAPA management
Deviations, suspected product defects, and other problems were reported, investigated, and recorded. An appropriate level of root cause analysis was applied during such investigations. The most likely root cause(s) were identified, and appropriate corrective and/or preventive actions (CAPAs) were determined and implemented in accordance with the applicable SOP. The effectiveness of CAPAs was monitored. These activities were performed in accordance with SOP GQA/022/R7, effective 15 May 2024.

Root cause investigations were carried out in accordance with the applicable SOP.

The records related to the deviation and root cause investigation for selected case were discussed. The corresponding root cause evaluation was documented separately.

The observation related to the Deviation and CAPA management was adequately addressed in the respective CAPA plan.

Quality risk management
An SOP for quality risk management was in place. The procedure covered different stages and phases of QRM, including risk assessment, risk control, and risk communication. Risk assessments were recorded in paper form and were not managed through any electronic application. The risk register was maintained in a logbook. Randomly selected risk assessment records were reviewed.

Regarding Cycloserine capsules 250 mg, a recommendation from the WHO-PQ Unit was in place concerning blend uniformity testing. The blending would be performed only in the in-process bulk containers and not in the V-blender (3200 L). A documented risk assessment addressing the relevant aspects and proposing risk mitigation measures was requested to be available during the inspection. In that context, a quality risk assessment, approved 27 June 2025, using the FMEA method, concluded that no critical or major risks were present. Both

batch sizes (63 kg and 152.80 kg) met PQ acceptance criteria, supported by statistical analysis demonstrating process consistency. As no commercial production had occurred since 2019, submission of updated batch records and the process validation report was requested once available.

The last DIRA report for the year 2024 was approved on 28 February 2025. The report was based on the review of quality events that occurred during the review period.

Product quality review

In general, Product Quality Reviews were conducted regularly and were documented annually in accordance with SOP GQA/015/R7 for Product Quality Review, effective 18 July 2023. The batches manufactured and other quality attributes pertaining to the previous year, from January to December, were considered for the product quality review.

As mentioned earlier in this report, no new batches of products within the scope of this inspection were manufactured. It was noted that the site had deployed a new system for the preparation and completion of ePQRs. In order to cover this system during the inspection, the relevant SOPs and a representative product were reviewed. The product was selected randomly for the period from 2 April 2024 to 1 April 2025 for Ibuprofen tablets 400 mg (FC), during which 19 batches were manufactured. CpK was calculated using a validated Excel sheet and the Minitab desktop application to generate the graphs. The process was described in the SOP, which required a detailed review of critical in-process and finished product results, both physical and analytical. Relevant statistical tools were applied, as applicable, to assess current process capability for drug substances and drug products, in accordance with relevant Guidance. Process capability analysis was not applicable to nutraceuticals. Statistical results were interpreted to confirm that processes were in control and capable. Graphical presentations of analytical results, yields, and Critical Quality Attribute trend charts, where more than three batches were available, were included, assessed for atypical trends or failures, and followed by appropriate improvement actions. Any significant improvements were documented. The review was based on not less than 25 consecutive batches manufactured within the last 12 months or, if unavailable, within the last 36 months. All listed elements, including reviews of materials, processes, batches, deviations, changes, stability data, complaints, CAPAs, post-marketing commitments, equipment and utility qualification, and technical agreements, were reviewed and addressed within the ePQR.

The Product Quality Review for Cycloserine capsules 250 mg, covering the review period from 01 January to 31 December 2024, showed that no batches were manufactured or released during this period. As a result, trend analysis for in-process controls, finished product testing, raw material usage, stability studies, OOS/OOT, deviations, and market complaints was not applicable. Equipment and utilities remained validated, and no issues were reported in purified water monitoring. Environmental monitoring results for Q1 to Q3 were found to be satisfactory. The review did not identify any quality, safety, or regulatory concerns, and no recommendations were issued.

The Product Quality Review covering the period from 22 April 2024 to 21 April 2025 showed that the manufacturing process and quality systems for Tenofovir Disoproxil Fumarate / Lamivudine / Dolutegravir tablets 300/300/50 mg remained in a state of control. No batches

were manufactured, released, reprocessed, or rejected during the review period. No OOS, OOT, deviations, market complaints, product recalls, or regulatory alerts were reported. Continuous Process Verification was not performed, as no batches were produced. Stability data and control sample reviews for previously manufactured batches were completed and were found satisfactory. Equipment and utilities qualification remained valid. No regulatory commitments, technical agreement issues, or significant changes were identified. No recommendations were proposed, as the review did not reveal any quality or compliance concerns.

A planner was available with the relevant information.

Batch release
The SOPs for batch release, i.e., Testing, Approval, and Disposition of IPC, Semi-finished and Finished Products, and Batch Release, were reviewed.

A release checklist was used to verify the correctness and completeness of documents and information before batch release. Batch release encompassed review of manufacturing records, packaging records, and the certificate of analysis. QA was supported by production, IPQA, analytical QA, and Quality Control teams in performing a preliminary review of source data. This was followed by a final checklist to verify that all required aspects, including QMS elements, were reviewed before batch release.

The test records and release documents, including the CoA, for Talc (USP) related to a selected batch were discussed.

Change Control Request
Change control was performed in accordance with the applicable SOP and managed in the respective software system. Selected change controls were reviewed in the system.

2. Good manufacturing practices for pharmaceutical products
Tenofovir disoproxil fumarate / Lamivudine / Dolutegravir tablets were submitted for WHO prequalification in July 2022 and were prequalified in April 2023, with the Puducherry site included as an additional manufacturing site; no commercial batches were manufactured at this site. Cycloserine capsules were submitted in November 2024, were prequalified in November 2025, and commercial production had commenced, with batches supplied for tender purposes.

The site maintained a quality management system to ensure consistent manufacture and control of products in line with regulatory requirements and marketing authorizations. Manufacturing, quality control, storage, and distribution activities were conducted according to defined procedures to ensure product quality, safety, and efficacy.

3. Sanitation and hygiene
An acceptable level of sanitation and hygiene was maintained in all aspects of medicine manufacturing. Sanitation and hygiene practices covered personnel, premises, equipment, production materials, containers, and cleaning agents. Potential sources of contamination were identified and eliminated through an integrated sanitation and hygiene program.

A general cleaning procedure was in place for the facilities, covering serial (batch-to-batch) and non-serial (product changeover) cleaning. The cleaning agents to be used were summarized in the Master List dated 28 May 2025.

Cleaning activities were recorded digitally in the software, in accordance with SOP for Handling and Managing the e-Logbook and e-Register dated 3 July 2025.

4. Qualification and validation

Validation and qualification activities were performed in accordance with well-established policies and documented procedures. The site used a validation life cycle management system to perform qualification activities digitally.

The Validation Master Plan was in place. The VMP described the key elements of the qualification and validation program and included commitments to maintain a continued validated state, including aspects of ongoing qualification and validation through regular revalidation and/or annual review (continued process verification).

The master list of the annual qualification and validation plan for the year 2025 was reviewed.

Validation and qualification activities were documented in the respective software system.

HVAC qualification

The technical area of the AHUs was on the 1st floor, over the production area. The ventilation system supplied inlet air through 20-micron filtration and was designed for local temperature and humidity conditions. A differential pressure of 5–20 Pa was maintained between rooms, with 90% recirculated air and 10% fresh air. Areas handling raw materials, in-process materials, and finished products operated under ISO Class 8 conditions, using HEPA-filtered air with a minimum of 20 air changes per hour. Temperatures were maintained between 21–25 °C, with relative humidity not exceeding 60%, while humidity-sensitive products were processed below 40% RH.

Details of AHUs and filter configurations were documented in the site annexes of the SMF. Temperature, humidity, and pressure in cubicles within the production areas and other relevant facilities were displayed, and any out-of-range conditions were notified through visual and audio alarms. The alarms were trended monthly, and the one related to the last month was reviewed in the QMS.

It was noted that the e-BMS was used only for the Phase IV production area, including the capsule filling area used for Cycloserine production. The BMS operation area was visited, and the system was checked for AHU-97, which was responsible for air supply to the capsule filling cubicle. The remainder of the facility was manually controlled, and a continuous environmental monitoring system was in place. Terminal HEPA filters with 99.97% efficiency were used, and integrity testing and filter cleaning were performed at defined intervals in accordance with approved procedures. Cleaning records for selected filters linked to AHU-97 were reviewed and verified. The validation of the 5 µm filtration system applicable to the capsule filling room in Phase 4 production was requested and subsequently reviewed to confirm that the filtration performance had been adequately qualified for its intended use.

Dirty filters were kept in a separate area and were washed and dried using automatic filter washing and drying equipment, which was maintained monthly. The water used for this activity was tested in accordance with SOP for Monitoring of Water System, effective 31 January 2025.

Settle plates were used for active air sampling, and the records, including equipment ID numbers, were documented in the respective logbook. Equipment usage was recorded in the e-log. The environmental monitoring records dated 21 November 2025 for sampling points, including point P16 related to the pilot production area and the V-blender room were available and reviewed.

The AHU units were operated continuously (24/7); however, they could be switched off during preventive maintenance or in the event of system failure, in accordance with SOP for Handling of Power Out and Breakdown Situations, effective 21 May 2025. The e-logbook for switching the units off and on was available and was reviewed.

Power interruption of the AHUs was studied for a period of three days, and a flowchart covering different scenarios was included in the SOP. The HVAC facility was accessed only by authorized personnel, and any interruption was notified on the Interruption Announcement panel.

The filter integrity test for the filter associated with AHU-97, executed on 07 July 2025 in accordance with SOP for Performance Qualification/Re-qualification for HVAC System, effective 12 November 2024, was reviewed in the respective software system. The process included leakage testing, non-viable and viable particle testing, and visual inspection of airflow.

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

Qualification of water systems for pharmaceutical use

SOP for Monitoring of Water System, effective 31 January 2025, covered the purified water system, demineralized water system, hot demineralized water system, and raw water/RO system, including generation, storage, and distribution at Strides Pharma Science Limited, formulation facility, Puducherry.

Source water (raw water) was defined as water derived from various sources, including a public water utility, a private water supply (e.g., tube well), or a combination of these sources. Documentation for sampling points, monitoring frequencies, and the testing schedule for December 2025 was available and was reviewed.

The water generation system at the manufacturing site was reviewed based on the provided engineering drawings and system schematics. The system was designed to treat raw water through defined pre-treatment steps, followed by RO and final purification prior to storage and distribution. Major equipment, utilities, pipelines, valves, and sampling points were identified, and sampling locations were defined at critical stages, including raw water, PSF, RO outlet, and RO permeate tank outlets.

All required parameters were monitored online, including TOC, conductivity, and UV intensity. The parameters were displayed on a panel linked to the digital monitoring system, and a daily report was printed out, which included information on any alarms initiated and the corresponding acknowledgements.

A comprehensive sampling plan was established, defining sampling points, frequencies, and test parameters for microbiological and chemical monitoring. The frequencies were differentiated based on water type and criticality, with purified water and hot DM water monitored on a routine basis, and raw water and RO water monitored at defined periodic intervals. Alert, action, and specification limits were defined for each water type, and a detailed monthly sampling schedule was in place to ensure systematic coverage of all designated sampling points. The document also specified responsibilities, sampling conditions, and provisions for handling deviations in sampling schedules, thereby supporting ongoing control and GMP compliance of the water systems. It was verified that the raw water tank was monitored once per year for chemical parameters and once per quarter for microbiological parameters, in accordance with SOP for Monitoring of Water System, effective 31 January 2025.

Trending of water system monitoring results, as well as environmental monitoring results, was performed in the form of Trend Review Summary Reports. The summary reports for EM and for the water system were available and reviewed. No OOT results were reported during Q3 2025.

Cleaning validation

Cleaning validation was performed in accordance with the respective SOP, which provided the procedure for establishing documented evidence that the cleaning methods used for equipment consistently and effectively removed residues of the previous product below predefined acceptance criteria, as well as residues of the detergents used in the cleaning solutions. The SOP also described the methodology for preparation of a cleaning validation programme for the facilities and for management of cleaning validation and the associated documentation.

The SOP applied to all product-contact manufacturing equipment and equipment parts within the scope of cleaning validation and ensured that all product-contact and non-product-contact surfaces of equipment used for the manufacture of pharmaceutical products were cleaned to an acceptable level to prevent contamination that could alter the safety, identity, strength, purity, and quality of the drug product, thereby ensuring patient safety. The SOP was applicable to all Strides facilities and subsidiaries involved in the manufacture of oral and topical non-sterile drug products and nutraceuticals for human consumption, including clinical trial batches.

Two types of cleaning were defined:

- Serial cleaning: performed between batches of the same product
- Non-serial cleaning:
    - after 21 days of batches of the same product
    - between two different products

The site performed periodic cleaning verification for each piece of equipment once per year, in addition to the initial cleaning validation performed using the worst-case molecule.

Relevant documentation was available, and the selected ones were discussed during the inspection.

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

Analytical Test Method validation
The development and validation of analytical procedures were carried out in accordance with applicable SOPs by the corporate R&D. Upon completion of the method development and validation by the sending laboratory, it was transferred to the site QCL, in accordance with the applicable SOP.

Two types of method transfer were defined:
- Direct method transfer for methods developed and validated by R&D for finished goods products
- Indirect method transfer for methods validated and received from the API vendor

Validation of the analytical methods used for cleaning validation was requested and discussed during the inspection.

Validation of computerized systems
The site used several software applications, with electronic integration across systems.

Validation of computerized systems was performed by the CSV, IT, or an approved outsourced team. The approach and requirements for system validation were defined in the Validation Master Plan for Computerized Systems. The CSVMP described the procedures to ensure that each system, when operated in accordance with defined instructions, consistently delivered its intended output and complied with company policy.

Computerized systems were validated in accordance with SOP for Computer Software Assurance, effective 21 July 2025.

A flowchart was included in the Technical Architecture Document for enterprise applications, which described the interfaces between respective applications.

Procedures were in place for computerized systems that defined their use and control. Appropriate segregation of roles between personnel responsible for business processes and those responsible for system administration and maintenance was observed. Details of user profiles and access rights to networks, servers, computerized systems, and software were documented and reviewed periodically. An up-to-date list of individual user rights for software, individual computer systems, and networks was maintained and was subject to change control.

Suitable security measures were in place to prevent unauthorized entry, manipulation, or deletion of data in computerized systems. A system for regular audit trail review was implemented in accordance with well-established SOPs. Measures were in place to protect audit trails from alteration or unauthorized deletion.

- Policy on Audit Trail Review
- SOP on Audit Trail Review – Manufacturing
- SOP on Audit Trail Review – Quality Control Laboratory

The practice of audit trail review by AQA (Analytical Quality Assurance) was verified through review of analysis audit trails, system audit trails, and log records in the chromatography software system associated with the HPLC instruments.

Computerized systems were periodically reviewed to determine whether they remained in a validated state or whether revalidation was required. The scope and extent of any revalidation were determined using a risk-based approach.

Chromatography software systems were networked and regularly backed up. Standalone computerized systems, such as FTIR instruments, were backed up using the respective application/server, with sets of daily, monthly, and annual backups provided. Backup tapes were stored in a fireproof cabinet in the IT office and with an offsite service provider.

Process validation
Validation, qualification, and hold-time protocols and their associated reports were managed electronically through the applicable e-system. A minimum of three consecutive batches was required to undergo process validation, with comprehensive in-process and finished product testing performed for data collection and statistical analysis prior to commercial release. Continued process verification was carried out as defined in the respective SOP.

Transport validation and routine monitoring were performed in accordance with the established procedures.

The observations related to Process validation were adequately addressed in the respective CAPA plan.

5. Complaints

Complaints related to potentially defective products were reviewed in accordance with the applicable SOP. A designated person, supported by adequate staff, was responsible for complaint handling and decision-making. QA managers were involved in all investigations and approvals related to complaints and recalls.

The SOP defined the actions to be taken, including assessment of the need for product recalls. Investigations were conducted to determine whether products were defective, and all complaints were documented and reviewed by the QA unit through the designated system. Where a defect was identified or suspected in a batch, other potentially affected batches were also assessed.

Where necessary, follow-up actions, including recalls, were implemented based on investigation outcomes. Complaint records were periodically reviewed to identify recurring issues requiring further action. Competent authorities were notified in cases involving faulty manufacturing, product deterioration, or other serious quality concerns.

Product recalls

An SOP for Handling product recalls was in place. A system was deployed to ensure the prompt and effective recall of products known or suspected to be defective. A nominated person was responsible for the execution and coordination of recalls and was supported by sufficient staff to manage all aspects with the required urgency.

Recalled products, when returned, were stored in a secure and segregated area until their final disposition was determined.

Competent authorities in all affected countries were promptly notified of any recall decision. Distribution records were readily available in the respective software system and contained details of direct customers and exported products, thereby facilitating an effective recall process.

The progress of recalls was monitored and documented, including reconciliation of delivered and recovered quantities. The recall system was periodically tested and evaluated to ensure its effectiveness.

At the time of the inspection, one recall was ongoing, which had been initiated on 3 July 2025 due to a stability failure.

6. Contract production, analysis, and other activities

Use of outside subcontractors for any step of manufacture was not applicable.

One contract laboratory was used for XRD testing of dolutegravir. Approval of the laboratory was managed by the Corporate QA team (CQA) responsible for vendor qualification, in accordance with SOP for Selection and Evaluation of External Service Providers. The up-to-date list of approved laboratories generated from LIMS included this laboratory.

A contract warehouse was used for storage of raw materials and packaging materials when additional capacity was required. The service provider was included on the approved vendor list.

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

Self-inspections were performed in accordance with SOP for Conducting Internal Audits, effective 4 August 2025. An annual internal quality audit plan was prepared and covered relevant systems and areas.

Inspections were performed objectively by a qualified team to ensure compliance with GMP requirements. All corrective actions were documented and implemented in the dedicated software system, and an effective follow-up program was in place. The self-inspection process followed written procedures covering key areas, including personnel, premises, equipment maintenance, storage, production controls, Quality Control, documentation, sanitation, validation, recalls, complaint management, and labelling.

A report was generated after each inspection, summarizing findings, evaluations, and corrective actions. Self-inspections were conducted at least three times per year, as defined in the

procedures. Management reviewed self-inspection reports and corrective actions during Quality Forum meetings to support continual improvement.

8. Personnel

The site maintained a structured organization for quality management, production, quality control, storage, and distribution.

The following organizational charts were provided:

- Organization chart of the site, included as Annexure 8 of the SMF
- Organizational chart of Production

The qualifications, experience, designation, and responsibilities of key personnel were summarized in Annexures 9 and 10 of the SMF. The job description of the production assistant responsible for granulation and blending was discussed.

The facility operated in three shifts, six days per week. The shift timings were as follows: the first shift operated from 06:00 to 14:00 hours, the second shift from 14:00 to 22:00 hours, and the third shift from 22:00 to 06:00 hours. The general shift operated from 08:30 to 17:00 hours.

9. Training

After employees completed induction training in accordance with the applicable SOP, their job roles were specified by the Head of Department (HOD). Based on the assigned role and job description, the HOD prepared the Job Role Matrix, initiated job role mapping, and forwarded the employee to the training manager for further processing in the LMS.

Technical training for all F2 unit personnel involved in manufacturing, processing, packing, or holding of products was conducted in accordance with the respective SOP. The training manager prepared the annual training calendar, covering GxP, role-specific training, OJT, and self-study, which was approved by the Head QA. HR issued a monthly training schedule specifying dates, times, and venues. All employees received GxP training at least once per year.

The training file of an operator was discussed, with particular reference to the SOP Handling and Managing the e-Logbook and e-Register. Training records, including the name of the trainer and assessment records, were available and were reviewed.

Records of training and evaluation were maintained by Quality Assurance. Training in current good manufacturing practices was also provided at regular intervals to ensure that employees remained familiar with GMP requirements.

10. Personal hygiene

Personnel underwent health examinations prior to and during employment, and periodic eye examinations were conducted for personnel performing visual inspections. Training on personal hygiene was provided, and strict hygiene practices were followed, including mandatory handwashing before entry into production areas. Personnel with illnesses or open lesions were restricted from handling raw materials, packaging materials, or medicinal products until they were considered non-risk. Employees were instructed to report any condition that

could potentially affect product quality. Direct hand contact with materials and products was avoided.

Personnel wore clean and appropriate protective clothing, including hair coverings. Reusable garments were stored in the dedicated lockers and washed daily. Smoking, eating, drinking, and carrying personal items were prohibited in production, Quality Control, and storage areas. Hygiene procedures and protective clothing requirements applied to all personnel, including temporary staff, visitors, and contractors entering production areas, in accordance with Personnel Hygiene and Medical Examination.

Personnel entering production facilities followed defined gowning requirements as described in the Entry–Exit Procedure for Production Block. The procedure described primary, secondary, and tertiary gowning, with colour coding defined as white for operators, grey for engineering personnel, brown for contract workers, and pink for housekeeping staff.

Contract workers were permitted to perform cleaning and housekeeping activities only outside the processing cubicles, in accordance with Cleaning Procedure for Pilot, Commercial Plant, and Production Accessories by Contract Housekeeping Personnel.

11. Premises

While TLD was manufactured at the Bangalore site, Strides intended to maintain the Puducherry site as a designated backup manufacturing site to ensure continuity of supply. For Cycloserine, only validation batches were manufactured at the Puducherry site. Both the pilot and commercial production areas of the site were used for manufacturing activities of the products within the scope of the inspection.

The site comprised designated blocks for production, packing, quality assurance, quality control, warehousing, and facility and engineering functions, as well as areas allocated for scrap handling, biomedical hazard management, and solvent storage. Activities were distributed across multiple floors. The ground floor accommodated warehouse, production, and packing operations. The first floor housed the quality control laboratory and utility technical areas. The second floor contained the purified water distribution system, stability chambers, reserve sample storage, quality assurance offices, and document archival facilities. A separate utility block supported compressed air generation and water pre-treatment activities. The drawings of material and personnel flow plans, as well as equipment layouts of the production areas, were provided in Annexure 11 of the SMF.

During the inspection, it was clarified that the production area was divided into four phases, in addition to the pilot production area. For the manufacturing of TLD and Cycloserine, the site primarily used the pilot production area; however, cubicles such as V-blender, granulation, and capsule filling areas in Phase I could also be used for the manufacturing of these products if commercial production were to be undertaken, depending on batch size. Capsule filling facilities in Phase IV could also be used for these products. It was noted that the products were manufactured in both the Pilot and Commercial production area.

All relevant facilities, including the tablet compression room and raw material staging rooms I and II, were covered during the facility tour. Primary and secondary packaging areas, including

bottle lines and capsule filling areas, were also inspected. It was noted that the tooling for TLD tablets was loaned from the donor and was returned to the donor after completion of production. Records related to this activity were available in the e-log and dated 10 April 2023.

The Building Management System (BMS) was used to monitor temperature and relative humidity in designated areas and to control mechanical, electrical, and electromechanical services within the facility. The system operated on a Direct Digital Control platform, with functions distributed across field controllers. The DDC network was connected to a central monitoring and data acquisition station through Design Insight. The BMS was managed in accordance with the applicable procedure.

The drainage in Tablet Inspection Room II in the pilot production area was not properly closed. This issue was addressed and corrected. In addition, all drainage points were checked, and any defects identified during the inspection were rectified.

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

12. Equipment

Use of facilities and equipment, including cleaning activities, was recorded in the e-log. Cleaning records for facilities and equipment were randomly verified in the system during the facility visit.

User management for the e-log system was handled by the corporate IT function based on requests from the site. The user privileges assigned to a production assistant responsible for granulation and blending were discussed.

Selected equipment and the respective documentation were reviewed to verify their qualification.

13. Materials

Materials were handled in accordance with written procedures, including:

- Receipt, Storage and Handling of Raw Materials and Packaging Materials
- Procedure for Result Handling and Disposition of Materials and Finished Products
- Receipt, Storage, Handling, and Dispatch of Finished Products in the Warehouse

Material receipt operations included inspection of the transportation vehicle, inspection and dedusting of material containers, weight verification, and verification of related documentation, including certificates of analysis, packing lists, invoices, challans, and the qualification status of suppliers and vendors. Physical inspection of material labels, batch numbers, and expiry details was also performed. An electronic checklist within the system was used to document these checks.

According to the PQ file for Cycloserine, the product could be packaged either in blisters or in bottles. The site had chosen blister packaging for Cycloserine. The site was advised that the validation process should encompass both packaging configurations for inspectors' review.

Vendors of raw materials and packaging materials were qualified at the corporate level and were listed in the approved vendor list maintained in the designated system. The qualification and monitoring of vendors were conducted in accordance with the following procedures:

- Selection, Evaluation and Approval of Vendors
- Vendor Quality Performance Review
- Vendor Audit
- TSE/BSE Risk Evaluation

Vendor evaluation records for the supplier of lamivudine and tenofovir disoproxil fumarate were discussed.

The warehouse for finished products, raw materials, and packaging materials was visited. Warehouse environmental conditions were controlled through a digital monitoring system, including temperature and humidity.

The site had two dispensing booths qualified as Class C. Nitrogen was available in the dispensing booths for use with sensitive materials. All sampling tools were cleaned and stored in the sampling area under QA supervision.

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

14. Documentation

Good documentation practices were maintained as part of the quality assurance system and ensured compliance with GMP requirements. Documentation defined specifications, procedures, and controls for materials and manufacturing processes and supported traceability, batch release decisions, and audit trails for investigation and validation.

A defined document control system was implemented at the site. An approved procedure described the preparation, revision, distribution, storage, and destruction of obsolete documents. All documents were identified by title, unique document number, revision status, and next review date. Master copies were maintained by Quality Assurance, and all batch-related data collection documents formed part of the respective batch records archived in QA.

Quality Assurance issued controlled photocopies of master documents to user departments. Upon revision, master copies were retained as superseded or obsolete, and all other copies were destroyed. SOPs were prepared and reviewed by the responsible departments at least every three years or when changes occurred, checked by the department head, and authorized by Quality Assurance.

All records were controlled in accordance with the respective SOPs, and changes were managed through the change control procedure. Retention periods for quality records were defined and followed as specified in the SOP. In addition to the QA archival area located on the second floor, an external document storage facility at Plot Re-survey Nos. 31/9 and 31/12 were used for document retention.

Master batch records were approved by Quality Assurance and were controlled through the DMS. QA issued batch manufacturing records and batch packaging records in accordance with process orders. Following review and approval, executed batch records were returned to QA for batch release and were subsequently archived in the documentation cell for the defined retention period.

Issuance of BMRs and BPRs was initiated based on a request from the user department in the system, which triggered the uploading of the product-specific BMR/BPR templates in the document management system application under QA supervision. SOP for Control of Documents, effective 10 July 2024, was established. BMRs and BPRs were printed by the QA department, and reconciliation was performed on a three-monthly basis accordingly.

Issuance of analytical data sheets was performed in accordance with SOP for Handling of Raw Data Sheets, Assigning Tests, Results Reporting and Disposition, effective 4 August 2025. Analytical sheets were generated either electronically using the respective application or in paper form. Product-specific templates were available in the LIMS and could be printed as a single controlled copy by the supervisor with a unique identification number.

Archiving of documentation was performed in accordance with the matrix defined in SOP for Document Management, effective 12 June 2025.

15. Good practices in production

The inspectors visited the manufacturing areas located on the ground floor, including changing rooms, raw material staging areas, tablet compression rooms, the pilot area, and Phase I, II, III, and IV production areas.

Handwashing and toilet facilities were provided prior to entry into the changing rooms. Separate changing rooms were available for Visitors and Employees (including casual workers). After removal of street clothes and footwear, personnel entered the first changing room, which was maintained as unclassified. Personnel were provided with shoe covers, aprons, hairnets, and beard masks, and crossed the bench before proceeding further.

Instructions requiring the removal of jewellery, watches, and mobile phones were displayed, and gowning instructions were provided.

Biometric and card access controls were in place before entry into the manufacturing areas. Garments were washed and ironed by the in-house laundry in accordance with SOP for Handling of Personal Uniform, effective 14 November 2025, which covered garments and footwear. Responsibility for the inspection of garments before washing was assigned to the laundry. A list of possible garment defects was included in the SOP. The SOP was available and was reviewed.

The dispensed material hold area was visited. The area was maintained at 21–25 °C and NMT 60 % relative humidity. Dispensed materials were verified for gross weight prior to transfer to the manufacturing areas.

16. Good practices in quality control

The Quality Control Department, including the Microbiology laboratory, was responsible for Sampling of packing materials. The department also performed environmental monitoring, water system sampling, and stability studies. The QA was responsible for sampling of Raw material, In-process, and finished product.

All testing samples were stored in the QC testing sample room under adequate supervision, together with reference standards used for qualification of working standards, supplied by the designated vendor. Chromatographic columns were also stored and monitored in the same room. Samples were assigned identification numbers in LIMS upon receipt. Reference standards were stored in the stability chamber monitored by a digital system.

All sampling activities were conducted in designated controlled areas under appropriate environmental conditions to prevent cross-contamination. Sampling activities were performed in accordance with the following procedures:

- Sampling, Testing and Approval of Raw Materials
- Sampling of Raw Materials
- Sampling and IPC Checks by QA

Quality Control laboratories were equipped for chemical, instrumental, and microbiological testing and were maintained under controlled temperature and humidity conditions using the digital system.

SOPs managed all QC activities, including sampling, testing, release, and retention of samples. Chambers were maintained to store stability samples under conditions as per regulatory requirements and monitored using a digital system, including one standby chamber. One chamber was under qualification at the time of the inspection. The alarm log for the last month was reviewed.

Testing records, certificates of analysis, and other Quality Control documents were maintained in accordance with data integrity principles and were readily retrievable. Laboratory equipment was qualified and calibrated in accordance with an established schedule.

Retention samples of each finished product batch were stored on the second floor under QA supervision for at least one year beyond the expiry date, in the final packaging, and under recommended storage conditions. Retention samples were maintained in sufficient quantity to allow at least two full re-examinations, if required. Raw material retention samples were kept for seven years.

Hold-time studies for empty capsules were performed, and the results were monitored and recorded in the respective BMRs.

The TLD 36-month stability study results were available and were reviewed. The study was performed on a selected batch, manufactured in May 2022. All test results were within specification. Samples were retrieved from the stability chamber on 2 June 2025.

The study was performed in accordance with the following SOPs:

- Designing and Handling of Stability Protocols
- Receipt, Incubation, and Withdrawal of Stability Samples

OOS investigations were carried out in accordance with SOP for Handling of Out of Specification Results, effective 28 April 2023. The procedure applied to all analytical results that fell outside specification limits or acceptance criteria, including those related to raw material specifications, in-process specifications, product release specifications, shelf-life specifications, packaging material specifications, water testing, and process validation samples, including hold-time study samples tested in accordance with established in-process or product release specifications. Environmental monitoring samples and water samples that did not meet acceptance criteria were handled in accordance with the applicable SOPs.

Once an OOS was identified in LIMS, it was automatically transferred to the respective software application, and an OOS investigation was initiated to identify potential laboratory errors, including Phase I and Phase II investigations and hypothesis testing, as applicable. One selected OOS investigation was discussed.

The microbiology laboratory was visited. Records for selected RO water samples were reviewed, including the inward log (paper-based), test worksheets, media preparation logs, GPT records (R2A media), and the applicable test methods and specifications.

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

Miscellaneous	
Samples taken	Not applicable
Assessment of the site master file	The Site Master File, effective 3 November 2025, was submitted 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 of ***Strides Pharma Science Limited*** located at ***RS No. 31, 32 and 33, PIMS Road, Periyakalapet, Puducherry - 605 014, India*** was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for pharmaceutical products 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 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
   https://www.who.int/publications/m/item/trs986-annex2

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   https://www.who.int/publications/m/item/annex-2-trs-957

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.
   Short name: WHO TRS 1010, Annex 9
   https://www.who.int/publications/m/item/trs1010-annex9

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   https://www.who.int/publications/m/item/annex-3-trs-1033

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   https://www.who.int/publications/m/item/annex-4-trs-929

6. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
   Short name: WHO TRS No. 1052, Annex 4
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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
   https://www.who.int/publications/m/item/trs957-annex3

8. 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
   https://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
   Short name: WHO TRS No. 1019, Annex 2
   https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
    Short name: WHO TRS No. 1044, Annex 4
    https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
    Short name: WHO TRS No. 1044, Annex 2
    https://www.who.int/publications/m/item/trs1044-annex2

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***
    https://www.who.int/publications/m/item/trs943-annex3

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.
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    https://www.who.int/publications/m/item/trs961-annex2

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    Short name: WHO TRS No. 981, Annex 2
    https://www.who.int/publications/m/item/trs981-annex2

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
https://www.who.int/publications/m/item/annex-3-trs-981

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
https://www.who.int/publications/m/item/tr961-annex14

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

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
https://www.who.int/publications/m/item/trs992-annex4

19. 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**
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

20. 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
https://www.who.int/publications/m/item/trs992-annex5

21. WHO Recommendations for quality requirements when plant – derived artemisinin 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
https://www.who.int/publications/m/item/trs-992-annex-6

22. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS No. 1033, Annex 4
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23. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
https://www.who.int/publications/m/item/trs966-annex10

24. 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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Short name: WHO TRS No. 1033, Annex 2
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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.
Short name: WHO TRS No. 1025, Annex 6
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27. 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. 1025), Annex 3.
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https://www.who.int/publications/m/item/trs-1025-annex-3-water-for-injection

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Short name: WHO TRS No. 961, Annex 13
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30. WHO good manufacturing practices for excipients used in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 1.
Short name: WHO TRS No. 1052, Annex 1
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