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WHO Prequalification Unit (PQT) - Inspection Services Team (INS)
WHO PUBLIC INSPECTION REPORT
Finished Product Manufacturer
WHOPIR

Part 1	**General information**
Manufacturers details	
Name of the manufacturer	Desano Pharmaceuticals Private Limited
Corporate address of the manufacturer	77D, KIADB Industrial Area, Jigani Bengaluru Karnataka 560105 India
Inspected site	
Name and address of the inspected manufacturing site if different from that given above	Desano Pharmaceuticals Private Limited Plot No. 600 to 612, Harohalli KIADB Industrial Area, 3rd Phase Bannikuppe Village, Kanakapura Taluk Ramanagara District, Karnataka, Bengaluru India, 562112 D-U-N-S Number: 766427365 GPS coordinates: North latitude: 12°39'32.7" N East longitude: 77°25'44.0" E
Unit/block/workshop number	Formulation Block-1
Inspection details	
Dates of inspection	From 15 to 19 September 2025
Type of inspection	INSP-FPP-2025-0012
Inspection record number	Routine inspection
Introduction	
Brief description of the manufacturing activities	The facility carries out manufacturing, packaging, and quality control of oral solid dosage (OSD) forms, specifically antiviral medicines, such as those used for HIV and other General medicines, for distribution to the domestic, US, and the rest of the world.
General information about the company and site	Desano Pharmaceuticals Private Limited, Bengaluru (FEI 3035948306), was constructed in 2023 as a formulation and finished-dose manufacturing site. The site has received a manufacturing license from the Government of Karnataka Drugs Control Department. The manufacturing plant is situated in a hygienic environment, free from dust, smoke, chemicals, & biological emissions. The facility

<table>
<tr><td></td><td>includes warehouses for raw and packing materials, finished goods, and provisions for the manufacture of tablets and capsules. For the testing of Raw material, packing material, in-process, and finished goods, a Quality Control Laboratory is available and well-equipped.

The manufacturing site is designed with a proposed maximum capacity of 3 billion finished formulations (tablets/capsules) annually. The currently installed and operational capacity is 1.1 billion annually, comprising Line 1 with 100 million and Line 2 with 1.0 billion.

M/s Desano Pharmaceuticals Pvt. Ltd. occupies a total plot area of 92,513.36 m², with all sides of the plot connected to road access. The site is located approximately 50 km from the Bengaluru city center, and the nearest airport, Kempe Gowda International Airport (IATA code: BLR), is situated approximately 85 km from the facility.</td></tr>
<tr><td>History of Regulatory Inspections</td><td>In the last five years, the site has been inspected by the following authority:
<table>
<tr><th>Name of the Authority</th><th>Dates of inspection</th><th>Scope of inspections (e.g., block, workshop, etc. inspected)</th><th>Outcome of inspection</th></tr>
<tr><td>USFDA</td><td>02-06 June, 2025</td><td>PAI Inspection for Formulation Block-1</td><td>Approved</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>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
- Production of exhibition batches and in-process controls
- Packaging and labelling of FPPs and intermediates
- Storage and distribution
- Laboratory controls
- Complaints and recall SOPs

Site areas visited:
- General production Formulation block I
- Warehouses
- QC laboratory—Physical, chemical, and microbiological</td></tr>
</table>

	- Water generation system utilities - HVAC system utilities
Restrictions	The site has not yet commenced the manufacture of commercial batches, and since the initiation of its activities, only three exhibition batches have been produced. Consequently, the scope of the GMP inspection for FPP was limited, as the assessment could not fully cover routine commercial manufacturing operations and was therefore focused primarily on the evaluation of the site's readiness for commercial production.
Out of scope	Not applicable
WHO product numbers covered by the inspection	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
CNC	Controlled Not Classified
CoA	Certificate of analysis
CpK	Process capability
CSV	Computerized System Validation
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 (or high performance liquid chromatography equipment)
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	Non conformity
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
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

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

1. Pharmaceutical quality system

A presentation was delivered during the opening meeting to introduce the site and its activities.

The pharmaceutical establishment maintained a Quality Management System to ensure compliance with Good Manufacturing Practices and regulatory requirements. The system covered all aspects of manufacturing, quality control, and distribution to guarantee the safety, efficacy, and quality of pharmaceutical products.

Operations were specified in written form to meet the essential GMP requirements. The procedures reviewed and discussed during the inspection were generally considered acceptable; however, improvements were requested in certain cases.

The company had a QM which described the processes required for the Quality Management System (QMS) and their application across the organization, in relation to the scope and development of the product. The sequence and interaction of these processes were illustrated in a process diagram

included within the QM. The organizational chart dated 30 May 2025 was included as Annexure-1 in the QM.

The following QMS activities were reviewed:

Management Review:
A Quality Management Review was held by the Quality Assurance department and was attended by all relevant department heads/managers in accordance with SOP for Management Review Meeting. The MR was scheduled to be conducted quarterly. The only Management Review (MR) meeting had been held in July 2025 since the establishment of the company. The Management Review covered the period from April to June 2025. The meeting minutes addressed the quality metrics and their trending, along with the identified tasks. Upon the inspectors' request for information on additional topics discussed during the Management Review, the management provided a separate document containing further items deemed relevant for such meetings. These items included deviations, CAPAs, and the outcome of the most recent U.S. Food and Drug Administration (FDA) inspection.

Handling of deviations
SOP for Deviation Management was reviewed. The SOP was applicable to deviations from established procedures that occurred during the execution of various activities within the facility.

The SOP described the classification and handling of deviations. The deadline for minor and major deviations was set at 30 days, with two possible extensions based on adequate justification. Critical deviations were required to be closed as soon as possible, with a target close-out of 15 working days. The risk analysis and root cause analysis related to deviations were also described in the SOP.

Deviations, suspected product defects, and other problems were reported, investigated, and recorded in the logbook "Deviation Register – 2025." The logbook was issued annually, and the 2025 edition was requested and reviewed. The logbook included information on serial number, date, deviation number, department, description of deviation, allotted by, classification, approval, CAPA number, and closure.

Selected deviations were reviewed together with the respective forms.
An appropriate level of root cause analysis was applied during such investigations. Deviations were closed after the Head of the user department reviewed and verified the CAPA's implementation and provided comments supporting the closure of the deviation. It was noted that deviations could be closed while the CAPA was still ongoing.

The site was advised to revise the deviation form to reflect the current practice by removing the terminology for planned and unplanned deviations, and to transfer the procedure for planned deviations to the SOP for Change Control.

CAPA management
SOP for Corrective Action and Preventive Action Management was reviewed. Deviations, suspected product defects, and other issues were reported, investigated, and documented using the corrective and preventive action form attached to the applicable SOP. An appropriate level of root cause analysis was applied during such investigations. The most likely root causes were identified using

justified methodologies, such as 5 Whys or Fishbone, and appropriate corrective and/or preventive actions were determined and implemented. The effectiveness of CAPAs was monitored.

CAPAs were raised in relation to deviations identified by the quality system or in relation to other deviations identified through inspections, internal audits, or other systems. A logbook for the CAPA Register – 2025 was available and was reviewed.

Change Control

Change Control Management was carried out in accordance with the SOP, which described the procedure for initiation, review, approval, implementation, monitoring, and closure of changes to validated systems, processes, procedures, and documents. The scope of the procedure applied to any change that had either a direct or indirect impact on the quality and documentation of a product, system, material, process, equipment, or procedure of the Formulation Blocks and QC Block at Desano Pharmaceuticals. A temporary change procedure was also incorporated into this SOP version, with appropriate scenario examples. Attachments to the SOP indicated that the Change Control process was adequately implemented in practice. The following forms were used:

- Change Control Form
- Additional Sheet for Change Proposal
- Impact Assessment Checklist for Change Control
- Risk Evaluation, Communication, and Mitigation

Selected Change Controls and the respective documentation were reviewed.

Disaster Management

The company had developed a draft SOP titled “Disaster Management,” which outlined comprehensive procedures for disaster recovery of computerized systems and servers to ensure business continuity in the event of system failures, natural disasters, or other disruptions. The SOP contained detailed procedures for failure observation, impact assessment, data recovery using third-party tools, and corrective action implementation.

Quality risk management

The company had established and maintained a Quality Risk Management system in accordance with ICH Q9 and GMP principles. SOP for Quality Risk Management was implemented. The procedure covered the different stages and phases of QRM, including risk assessment, risk control, and risk communication. During the inspection, it was observed that QRM principles had been systematically integrated across multiple operational domains such as training programs, self-inspection activities, complaint and product recall handling, qualification and validation of equipment and processes, and vendor qualification.

The risk register was reviewed.

Product quality review

As only exhibit batches had been manufactured, the preparation and submission of a PQR were not required. However, relevant data and reports, including batch records, validation data, analytical results, and stability data, were available as part of the site addition variation. The first PQR was expected to be prepared following the initiation of commercial production.

SOP for Annual Product Quality Review was available and was reviewed.

Trend analysis

The SOP for Trend Analysis was followed in the QA/QC unit to establish a standard procedure for preparing and reviewing trend data. This included Environmental Monitoring and Compressed Air data trending in the Microbiology Laboratory, as well as Water Analysis trend identification in the QC and Microbiology Laboratories. For the trend analysis of QMS parameters, the activity was defined in the respective SOP. However, due to the absence of main activities and production, the practice had not yet been initiated.

Batch release

SOP on Batch Release for Finished Product defined the procedure for the approval and release of commercial batches of finished pharmaceutical products, ensuring compliance with cGMP and regulatory requirements. It outlined the responsibilities of QA, QC, Production, and Plant Management in reviewing batch manufacturing and packing records, analytical and microbiological data, and handling deviations or out-of-specification results. The process included sampling, analysis, documentation review, and the use of checklists to verify completeness and compliance before batch release. Only qualified and authorized personnel were permitted to release batches. The SOP also detailed the flow of batch release, the required records, and the management of discrepancies, supporting traceability and product quality assurance throughout the release process. According to the procedure, the QA Head / Qualified Person was responsible for batch release and was also responsible for the approval and monitoring of executed BMR/BPR. The respective job description was reviewed.

The observations related to the various activities within the Quality Management System were addressed in the respective CAPA plan.

2. Good manufacturing practices for pharmaceutical products

The site maintained a GMP-compliant quality management system to ensure that pharmaceutical products should be consistently manufactured and controlled in accordance with regulatory requirements and marketing authorizations. The GMP system aimed to minimize manufacturing risks and ensure product quality, safety, and efficacy.

The manufacturing process flow chart for Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate Tablets (50 mg/300 mg/300 mg) described the four main stages. The process was required to ensure the quality through stepwise controls on weight, hardness, friability, disintegration, and appearance. Manufacturing processes were defined, validated, and systematically reviewed to confirm compliance with established specifications. Resources were provided, including qualified personnel, facilities, equipment, materials, and documented procedures.

Production and quality control activities were conducted according to written instructions, with records maintained to demonstrate compliance. Deviations were documented, investigated, and addressed through corrective and preventive actions. Batch records ensured full traceability of manufacturing and distribution.

A recall system was in place, and complaints and quality defects were investigated, with appropriate measures taken to prevent recurrence. (Refer to section 5 & 6 – Complaints & Recalls)

3. Sanitation and hygiene

SOP on Cleaning and Sanitation of Production Area was reviewed. The SOP outlined the procedures for cleaning and sanitizing production areas. It defined responsibilities, cleaning tools, and step-by-step methods for maintaining hygiene across ceilings, walls, equipment, and floors. The SOP specified the use of specific disinfectants. Disinfectant solutions were changed weekly and applied with a minimum contact time of 10 minutes. Effectiveness studies of the mentioned solutions were reviewed and found satisfactory. Cleaning frequencies were defined for different zones and equipment, and all activities were documented in standardized records.

In addition, SOP on Cleaning of Equipment and Area was available and reviewed. The SOP described the procedures for cleaning equipment and production areas. It defined responsibilities, cleaning methods, and types of cleaning based on manufacturing stages and product changes.

The SOP also covered cleaning frequencies, handling of idle equipment, labeling requirements, and documentation protocols.

4. Qualification and validation

Validation and qualification activities were performed according to established policies and documented procedures. The Validation Master Plan was in place. The VMP defined the key elements of the qualification and validation programme, including principles of commissioning and qualification, URS, risk assessment, CSV, facility qualification, process validation, validation of analytical methods, spreadsheet validation, disinfectant efficacy validation, transportation validation, and cleaning validation. All decommissioning activities were required to undergo the change management procedure in accordance with the relevant SOP, supported by an approved protocol.

The VMP also included provisions for maintaining continued validation status, covering aspects of the ongoing qualification and validation programme through regular re-validation and/or annual review (continued process verification).

The Annual Validation Planner for Equipment, Instrument, Utility Qualification, Computerized Systems, and Cleaning Validation for 2025 and 2026 was reviewed. In general, equipment and premises were calibrated or qualified in accordance with predefined procedures. Relevant qualification, calibration, equipment preventive and breakdown maintenance procedures, as well as calibration/qualification and maintenance programs, were in place. Records related to calibration, qualification, and preventive maintenance were complete, up to date, and well-documented, supporting consistent equipment performance and operational reliability.

Validation and qualification activities were documented in the form of protocols and reports.

The Annual Instrument Calibration Schedule related to the QC Laboratory was also provided and reviewed.

Calibration or qualification records for the selected equipment and premises were reviewed.

Validation of heating, ventilation, and air-conditioning systems
The AHUs catering to the blending room and the compression room were visited, and the respective monitoring of pressure and temperature was verified. The systems were manually monitored at the time of inspection, since the BMS and EMS software systems were still under qualification. The monitoring room was also visited, and the systems were briefly demonstrated during the inspection.

During the visit, it was noted that, as no activities were being carried out in the production area at the time, the differential pressure, temperature, and relative humidity were recorded once in the morning, after which the respective AHU was switched off continuously for a 7-day period, in accordance with SOP for Monitoring and Recording of Differential Pressure, Temperature, and Relative Humidity in Production. Each AHU was switched on every 8th day for recording differential pressure, temperature, and relative humidity in the morning for a duration of one to 1.5 hours. Cleaning activities in the processing area were performed on a daily or weekly schedule. If any production activity was planned, the respective AHU was switched on as per the request form "Intimation Form for AHU ON/OFF".

This practice had been risk assessed based on the study "Continuous AHU Shutdown Study for a Period of 7 Days," which was reviewed during the inspection.

Validation of water systems for pharmaceutical use
The water generation system was visited. The origin of the water was the well, and the system was distributed across two levels of the facility. The system was equipped with continuous monitoring and control systems to record temperature, TOC, velocity, conductivity, flow rate, and pressure. In the event of any deviation from the defined critical parameters, the automatic drainage system was triggered to discharge the water, thereby preventing its use. Alarm logs were randomly selected and reviewed. It was noted that alarms for certain parameters, such as tank level or pressure level, could be automatically inactivated, while others required acknowledgement by technicians.

The water pre-treatment facility, located in a separate building from the main manufacturing block, was also visited during the inspection. This dedicated area houses the initial stages of water purification, including raw water storage, chlorination, multigrade filtration, and softening.

SOP for CIP (Cleaning in Place) and Sanitization Procedure was available and applicable for the chemical cleaning and sanitization of the UF/RO membrane of the water pretreatment system. The sanitization process of the purified water generation system was described in the respective SOP. In addition, another SOP was available for the procedure for sanitization of the purified water storage and distribution system.

The schematic drawings of the purified water system were attached as Appendix 7 of the SMF. The water system had been qualified in three phases (I, II, and III), which was reviewed and found satisfactory.

Cleaning validation
Cleaning validation was carried out in accordance with the SOP for Cleaning Validation Programme.

At the time of inspection, only the product within the scope of this inspection was planned to be manufactured at the facility. Therefore, the same product was also considered as the previous product. The cleaning validation protocol for Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate Tablets 50/300/300 mg was available and reviewed. The protocol addressed the removal of Tenofovir residue from the equipment/environment.

The laboratory was, for the time being, using only the swabbing methodology, as the rinse methodology was not required due to the type of equipment used; however, the rinse method was described in the protocol.

The highest toxic molecule was determined to be Tenofovir Disoproxil Fumarate. Sample details were defined. The analysis was carried out in accordance with Cleaning Verification Standard Test.

The MACO calculation, performed in accordance with the applicable SOP was described in the protocol, taking into account ADE/PDE value, the maximum daily dose, and the minimum batch size. Equipment sampling details were defined and illustrated in the protocol. The MACO calculation had been reviewed and approved on 19 December 2024.

The respective cleaning validation report was available and had been approved on 24 December 2024, immediately after the last exhibition batch.

SOP for Prevention of Cross-Contamination in Production Areas was in draft version and was reviewed. No suggestions were deemed necessary.

Analytical procedure validation
Refer to the respective information under the section entitled “Good practices in quality control”.

Validation of computerized systems
The SOP for validation of computerized systems was part of the VMP and was reviewed. In general, the computerized systems used during the manufacturing processes were validated in accordance with the principles of quality risk management, with the level of validation commensurate with the identified risks, complexity, and intended use. An impact assessment was required to be carried out to define the GxP system’s category.

The list of computerized systems used onsite was provided, and the documentation relevant to the validation of selected computerized systems was spot-checked.

The qualification of the software systems was carried out by the vendor and was supervised and approved by the site (Head QA).

The site was advised to prepare a traceability matrix to link each test and the respective evidence to the corresponding URS, to ensure that all aspects of the URS were covered during the qualification of the systems.

Procedures were in place for computerized systems, defining their use and control. Appropriate segregation of roles between personnel responsible for business processes and personnel responsible for system administration and maintenance was noted. 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, computer systems, and networks was maintained and subjected to change control.

Suitable security measures were in place to prevent unauthorized entry, manipulation, or deletion of computerized systems' data. A system for regular review of audit trails was established in accordance with SOP for Recording and Reviewing of Raw Data and Audit Trail. The SOP had been approved on 11 September 2025 and was in the process of training prior to becoming effective. This SOP was applicable to the QC laboratory, while in the production area, audit trail review was performed as part of BMR/BPR records. The review of audit trails associated with BMS and EMS would be included in their respective SOPs upon completion of the systems.

Computerized systems were periodically reviewed to determine whether they remained in a validated state or whether revalidation was required. The scope and extent of revalidation were indicated in the list of computerized systems.

At the time of inspection, the site was not using any software applications for activities such as LIMS, handling of QMS parameters, or sample management. The software applications in use were limited to temperature monitoring and equipment used in the QC laboratory. Measures for protecting audit trails from alteration or unauthorized deletion were in place and were verified by confirming that the systems' audit trails could not be switched off. This functionality was randomly tested. Additionally, during the qualification of the software systems, the functionality of the audit trail was tested and verified.

Manual integration was prohibited in accordance with SOP for Good Chromatographic Practices. According to this SOP, only in cases of related substances, where peak integration was not feasible through the auto integrator, integration parameters could be modified throughout the run. This specific section needed to be revised for clarity purposes.

SOP for Data Integrity was available and reviewed. The SOP ensured that manual and electronic data generated during GMP processes were implemented through the quality management system. A Data Integrity Policy was also in place at the site.

Process validation

The company had established SOP on Process Validation Programme, which detailed a comprehensive approach to process validation to ensure that all manufacturing processes consistently met predefined quality standards. The SOP covered the entire validation lifecycle, including process design, process qualification (prospective, concurrent, and revalidation), and continued process verification. It clearly defined departmental responsibilities, risk assessment, control of critical

parameters, sampling and testing strategies, and statistical evaluation. It also specified documentation requirements and mandated revalidation after significant changes or at set intervals to maintain ongoing product quality and compliance.

The Master Formula Record was available and reviewed.

Hold time studies

The company has established and implemented a procedure for hold time studies. These studies have been conducted for various intermediate stages as well as bulk products. The review of study results for the I- and II-layer lubricated blend product and coated tablets from a selected batch was found to be satisfactory.

5. Complaints

At the time of inspection, the company was not producing commercial batches; therefore, no complaints had been received from the market. However, it was verified that a complaint management procedure was established.

SOP on Handling of Market Complaints was available and reviewed. The SOP outlined the procedure for receiving, investigating, and resolving market complaints related to drug products. It applied to complaints received through verbal, written, or electronic communication from customers, regulatory bodies, or other stakeholders.

Complaints were classified as critical, major, or minor based on their potential impact on product quality and patient safety. The SOP defined departmental responsibilities (QA, QC, Production, etc.), investigation methodologies (e.g., Fishbone, 5-Why, FMEA), and documentation requirements. Key elements included complaint registration and tracking, sample analysis and comparison with control samples, root cause analysis and CAPA implementation, communication with regulatory authorities and customers, and defined timelines for investigation and closure. A logbook for complaint registration was in place.

6. Product recalls

A system was in place to ensure the prompt and effective recall of products known or suspected to be defective. The Head of Quality Assurance was responsible for executing and coordinating recalls, supported by sufficient staff to manage all aspects with the required urgency.

A written procedure for recall activities was established, outlining the process for initiating, managing, and closing product recalls. The SOP applied to both statutory and voluntary recalls of finished pharmaceutical products from domestic and export markets.
Key elements included:

- Recall classification and depth
- Defined responsibilities
- Risk-based assessment to determine recall necessity and scope
- Communication protocols
- Effectiveness checks
- Documentation requirements

As the company did not produce commercial batches at the time of inspection, there were no actual recalls or mock recalls performed. The SOP mandated mock recalls every three years in the absence of real events.

7. Contract production, analysis, and other activities

A list of contracts with external laboratories to perform QC testing was available in Appendix 4 of the SMF.

A service agreement was selected and reviewed. The laboratory had been audited by the site on 26 August 2024. It was verified that the contract acceptor permitted the contract giver to audit the facilities and activities of the contract acceptor or mutually agreed subcontractors. For contract analysis, it was confirmed that the final approval for release was given by the authorized person in accordance with GMP and the marketing authorization requirements, as specified in the contract and in the respective CoA.

The contract between the contract giver and the contract acceptor clearly defined the responsibilities of each party, including outsourced activities and communication. Provisions were included for documentation systems, training, subcontracting, complaints, and recall handling.

A list of vendors providing different materials, including APIs and excipients, was available. Vendors were managed in accordance with SOP for Vendor Management. An audit plan was provided at the time of inspection.

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

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

The company has established, implemented, and maintained a documented self-inspection system. The procedure was governed by SOP on Self-Inspection, which outlined the internal audit process to ensure compliance with cGMP. The SOP mandated biannual inspections across all departments, with provisions for additional audits in response to quality events such as recurring deviations. It clearly defined roles and responsibilities, planning and execution protocols using standardized checklists, classification of observations (critical, major, minor), and a structured CAPA process. The SOP also included auditor qualification criteria and emphasized confidentiality of findings to support continuous improvement and regulatory compliance. A qualified pool of auditors, primarily composed of department heads, has been established. Recent self-inspection reports were reviewed for the microbiology laboratory, production, and warehouse, with all associated records found to be complete and in order.

Arrangements were in place to ensure the manufacture, supply, and use of the appropriate starting and packaging materials. This included the selection and monitoring of suppliers, as well as verification that each delivery consisted of the correct materials sourced from the approved supply chain. These activities were governed by a written procedure on Vendor Management. Vendor performance was evaluated annually, with 70% of the assessment based on quality standards and the remaining 30% based on purchasing criteria

9. Personnel

The firm had 73 employees. It operated with general business hours from 9:00 AM to 6:00 PM, Monday to Saturday.

The company had established a clearly defined organizational structure, as documented in the approved site organogram. The chart outlined reporting lines and departmental responsibilities across all key GMP functions and included trainee positions.

Job Descriptions were prepared for all positions, outlining the roles and responsibilities of each staff member. Personnel have been duly informed of their respective JDs, which were acknowledged and signed. The management and control of JDs was governed by SOP on Preparation, Approval, Revision and Control of Organogram and Job Responsibilities. During the inspection, JDs for various roles—including key positions across QA, QC, Production, Engineering, Warehouse, and Management Trainees—were reviewed.

Observations related to Personnel have been addressed in the respective CAPA plan.

10. Training

The company had established and maintained a comprehensive training program supported by relevant documentation. At the time of inspection, the training program was paper-based. SOP for Training Program outlined a structured methodology for identifying training needs, conducting various types of training—including induction, on-the-job, planned, unplanned, SOP-specific, refresher, and external—and maintaining training records to ensure staff competency in accordance with cGMP and departmental requirements.

Roles and responsibilities of HR, QA, and departmental heads were clearly defined, along with procedures for trainer qualification, training evaluation, and certification. During the inspection, training records for selected sessions conducted in 2025 were reviewed, including cleanroom sanitization of production areas, environmental monitoring procedures, data integrity, and deviation management. Job-specific training records for selected personnel were also verified and found to be appropriately documented.

11. Personal hygiene

The company has established and implemented a comprehensive SOP describing good hygiene practices, i.e., SOP for Personal hygiene. All personnel were provided with appropriate protective clothing and followed documented hygiene procedures, including hand washing, gowning, and restricted access to production areas. Regular training on hygiene practices was conducted, and training records were maintained. Good hygiene practices were strictly followed. Eating, drinking, chewing, smoking, and storage of food or personal items were prohibited in production, laboratory, and storage areas. Personnel maintained a high standard of personal cleanliness, including trimmed nails and appropriate grooming of hair and beard. The use of jewelry, cosmetics, and strong fragrances was not permitted in critical areas.

All staff underwent pre-employment and annual medical examinations to ensure their fitness for work in pharmaceutical manufacturing. No employees with health conditions that could adversely affect

product quality were observed in the manufacturing or quality areas. Medical records were kept confidential, but were made available for verification during the inspection

12. Premises

Storage areas

The storage areas were inspected on the second day of the inspection. The facility comprised high-rack warehouses for raw materials and finished products located on the ground floor, while the packaging materials warehouse was situated on the first floor of Block 1. Access to these areas was through the general corridor.

Overall, the storage areas were found to be clean, well-organized, and of adequate capacity to support the orderly storage of various categories of materials and products. Proper segregation was observed between different types of items, including starting and packaging materials, intermediates, bulk and finished products, as well as products under quarantine, and those that were released, rejected, returned, or recalled.

The facility was equipped with one receiving bay and one dispatch bay. These bays were physically separated and designed to protect materials and products from environmental exposure. The receiving area was appropriately designed and equipped to allow for the cleaning of incoming containers prior to storage, when necessary.

Temperature within the warehouse areas was maintained below 25°C. Monitoring and recording of temperature were performed daily. A dedicated storage room was available for Tenofovir API, which requires storage conditions of 2–8°C. This room was continuously monitored to ensure compliance with the specified conditions. However, relative humidity was not controlled or monitored in the general storage areas. Temperature/humidity mapping reports of the finished products warehouse were reviewed.

The company was in a transition phase toward implementing an Environmental Monitoring System (EMS) in the storage areas to enhance control and compliance.

Pest control traps were observed to be installed outside the warehouse areas. Pest control activities were outsourced to an external service provider, a company specializing in pest management. The relevant SOP, for Pest control management and associated records were reviewed during the inspection and found to be satisfactory. The documentation confirmed that pest control activities were conducted regularly and in accordance with GMP requirements, ensuring that the storage areas remain free from pest-related risks.

Production areas

The production areas at Desano Pharmaceuticals were purpose-built for manufacturing oral solid dosage forms (tablets and capsules), primarily located in Block 1 (Formulation block), with packaging operations on Level 0 and production on Level 2, all designed to meet cGMP standards. The facility comprised two production lines: Line 1, with an annual capacity of 100 million units, and Line 2, with a capacity of 1.0 billion units, together supporting an installed annual capacity of 1.1 billion units and a proposed maximum of 3 billion units. Both lines were qualified; however, at the time of inspection, commercial production had not yet commenced—only exhibit batches had been produced on Line 1, while Line 2 remained in standby mode. The production areas were spacious, well-maintained, and

clean, featuring dedicated zones for granulation, compression, coating, and packaging, as well as supporting spaces like airlocks and gowning rooms to ensure controlled environments and minimize cross-contamination. Airlocks were installed before entry to critical rooms, with appropriate pressure differentials maintained, and a clean corridor principle was applied across both lines. Each line was equipped with modern equipment and followed unidirectional flow for materials and personnel, ensuring efficient, compliant, and contamination-free operations. Areas for the critical operations were classified as clean zone D. All surfaces, including floors, walls, and ceilings, were durable, smooth, and easy to clean, ensuring high standards of hygiene. Production areas were supplied with high-quality air that met their designated cleanroom classifications, ensuring appropriate levels of cleanliness and particulate control. Temperature and humidity were regulated and monitored in areas where environmental control is critical.

The facility housed a compressed air unit located on the utilities floor. Compressed air was utilized for two distinct purposes: production-related processes and the operation of equipment and machinery. The compressed air that came into direct or indirect contact with the product was oil-free and passed through a series of graded filtration systems to ensure its purity. Regular monitoring and maintenance of the filtration system were conducted to ensure compliance with air quality standards and to prevent any risk of contamination. Compressed air used for equipment movement or utility functions did not contact the product and therefore followed a different quality standard, though it was still maintained to ensure operational reliability and safety.

Observations related to the Premises have been addressed in the respective CAPA plan.

13. Equipment

In general, equipment in storage, manufacturing, and quality control areas was observed to be suitably designed, appropriately located, properly maintained, calibrated/qualified, and utilized in accordance with their intended use.

Equipment was randomly selected, and documentation to verify their qualification was reviewed.

Observations related to the Equipment were addressed in the respective CAPA plan.

14. Material

The company's material management system was entirely paper based. The management of raw and packaging materials was governed by several SOPs, such as SOP for Receipt, Storage and Handling of Raw Materials and Packing Material, SOP for Storage and Handling of Raw Material, Packing Material, and Finished Product, etc. Material receipt operations were found to be comprehensive and included inspection of the vehicle, inspection and dedusting of material containers, weight verification, review of accompanying documentation (e.g., certificates of analysis, packing lists, invoices, etc.), verification of supplier and vendor qualification status, physical inspection of material labels, batch numbers, and expiry dates.

Upon receipt, a Goods Receipt Note (GRN) was issued, and an internal code was assigned to each material. Materials were labelled according to their status—quarantine, approved, rejected, or returned—using a color-coded label system. Quarantine labels were issued by warehouse personnel, while sampled and approved labels were affixed by QC personnel. Relevant SOPs, such as SOP for Sampling of raw materials, and SOP for Sampling, testing, and release of packaging material, were in

place. Materials were appropriately segregated based on status, and measures to prevent mix-ups were in place and found effective.

Management of rejected and returned products was performed according to the SOP for Handling of rejected and expired materials in the warehouse, and SOP for Handling of return materials from production. Both procedures were reviewed and found satisfactory. At the time of inspection, there were no rejected/expired and returned materials. It was, however, noted that the related logbooks were in place.

The company had planned to transition to a QR code-based material management system, which was expected to improve traceability and reduce the risk of human error.

Dedicated areas for material handling were in place, including one separate weighing area for received materials, two sampling areas, and two dispensing rooms, which were designed to minimize the risk of mix-up and cross-contamination through both technical and administrative controls, such as airlocks, differential pressure systems, gowning procedures, and use of Reverse Laminar Flow (RLF) units. The layout and design of these areas were found to be appropriate for their intended functions and compliant with GMP requirements. SOP for Sampling, Testing, and Release of Packing Material was available and used by QA for the respective testing.

The raw material and packaging material stock register for Tenofovir, used in different activities including the three exhibition batches, was checked. The logbook was maintained in accordance with the applicable SOP.

The receipt, storage, and usage of laboratory chemicals were managed in accordance with SOP. The usage of chemicals in the laboratory was recorded in a logbook, and additionally, the site had established a template for a chemical index for supervisory purposes. The storage of reagents was checked and found to be appropriate.

Reference standards:
Whenever official reference standards existed, these were preferably used and only for the purposes described in the relevant monograph. The USP reference standards were provided by a supplier. In-house reference standards were prepared and stored in the same storage room as the official reference standards, either in the refrigerator or at room temperature in designated desiccators, as required.

As an example, records of preparation of Dolutegravir Sodium WS working standard against the USP reference standard were reviewed and found to be satisfactory.

All reference standards were properly labelled with name, batch/lot and control number, date of preparation, shelf life, potency, and storage conditions, and were stored in a manner that safeguarded their quality. Tenofovir retained samples were also kept in a separate refrigerator in the reference standards storage room under the supervision of QA. The temperature of the refrigerators was monitored using digital thermometers, and during the inspection, the alarm function was tested to verify receipt of both the buzzing alarm and the SMS notification.

The reference standards were handled in accordance with the respective SOP, and their consumption was recorded in the respective logbook.

Observations related to the Materials were addressed in the respective CAPA plan.

15. Documentation

Good documentation practices were maintained as part of the quality assurance system, ensuring compliance with GMP requirements. Documentation defined specifications, procedures, and controls for all materials and manufacturing processes, and ensured traceability, batch release decisions, and audit trails for investigations and validations. SOP for Procedure for Preparation of Standard Operating Procedures was available.

Documents were designed, reviewed, approved, and distributed in accordance with regulatory requirements. In general, they were clear, legible, and systematically organized to prevent errors. Regular reviews and updates were conducted, and measures were in place to prevent the unintended use of superseded versions. Data entries were legible, indelible, and appropriately spaced, with any alterations signed, dated, and traceable. Records were completed in real time and retained in accordance with SOP for Issuance, Receipt, Retrieval, Storage, Retention, and Destruction of Documents.

SOP for Data Backup and Restore was available and reviewed. The data backup and restore flowchart was attached to the SOP as Annexure-1. The chromatography software systems were networked and connected to the server. A second backup was performed monthly on a hard disk. However, the specifications of the hard disk were not defined in the respective SOP, and the site was recommended to include them.

A draft SOP for Disaster Recovery Data Management was in process, and a template for network architecture had been prepared to illustrate the IT infrastructure, including the firewall and switches in different areas. The site was recommended to include full details of the IT infrastructure in the flow diagram.

The site had a dedicated server room, and periodic manual backups were performed using an external hard drive; however, the company did not maintain a remote backup system located off-site. Inspectors were informed that the implementation of a remote backup system was included in the company’s plans.

Evidence of data restoration performed on 30 July 2025 was available and reviewed.

Testing procedures were validated, and specifications were defined and periodically checked, as necessary, to ensure compliance with revised editions of the pharmacopoeia or other applicable requirements.

Batch number allocation was recorded in the respective logbook. The record included the date of allocation, product identity, and batch size.

SOP for Document Receipt, Storage, Issuance, and Retrieval from the Document Room was available and reviewed. The process was verified through the successful retrieval of documentation upon the inspectors’ request.

The following SOPs were also available:
- SOP for Control, Distribution, Retrieval, and Archiving of SOPs
- SOP for Issuance, Receipt, Retrieval, Storage, Retention, and Destruction of Documents.

The Batch Packing Record template (paper-based) used for BPR was identified with a specific number. The records for a batch were randomly checked to verify that packaging activities were documented at the time of performance, with the date and the responsible person clearly identified by signature. The records included details of the product, batch numbers, quantities, equipment used, operators involved, in-process controls, deviations, and reconciliation of materials and yields.

16. Good practices in production

This section has been addressed in previous sections.

The company did not carry out any rework or reprocessing activities. This was clearly stated in the Quality Manual and Site Master File, which confirmed that such operations were not part of the current manufacturing practices. Consequently, no records related to rework or reprocessing were observed during the inspection, in alignment with the company's defined quality policy in the mentioned area.

17. Good practices in quality control

The quality control laboratory areas were visited, which were situated in Block-2 (Admin, QA/QC, and R&D block).

The Quality Control Department was responsible for the sampling and testing of raw materials, packaging materials, in-process samples, and finished products. The department also handled environmental monitoring, water system sampling, and stability studies.

The microbiology laboratory, while part of the QC department, was physically separated and had its own dedicated entrance. The laboratory was well-designed, offering ample space for all activities, and incorporated both administrative and technical controls to prevent contamination and cross-contamination. It was organized into specialized zones, including rooms for media preparation, culture handling, decontamination, incubation, and 6 microbial limit testing (MLT) rooms – 3 of which were operational at the time of inspection.

There were four stability chambers in the QC laboratory with the following ranges:
- 30 °C / 75% RH – Long term
- 40 °C / 75% RH – Accelerated
- 25 °C / 60% RH – Long term
- 30 °C / 65% RH – Long term

The chambers were linked to a software for temperature and humidity monitoring.

The stability study protocol for Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate Tablets 50/300/300 mg was provided and reviewed. The protocol defined stability studies on three exhibit batches of the product under the specified conditions for regulatory submission and shelf-life assignment. The scope was to validate the stability of the product under different conditions. The planned shelf life was 2–3 years, with testing scheduled for 48 months.

The protocol specified the stability tests and corresponding specifications and included a table defining the testing and review timelines. Bracketing and matrixing approaches were not applicable. Evaluation and reporting of results were also defined in the protocol. No OOS results had been reported to date.

A stability study summary report was available and reviewed for product stability testing under accelerated conditions at 40 °C / 75% RH in 90's pack, 250 cc HDPE bottles with 53 mm CRC containers. All scheduled time points (0M, 1M, 3M, 6M) were completed in accordance with the stability protocol. The final report was planned to be prepared at the conclusion of the study after 48 months. The alarm log of a chamber for a selected period was provided and reviewed.

Throughout the QCL facility, the temperature was monitored.

The water system sampling was reviewed during the inspection. A schedule for purified water sampling for the year 2025 was available and reviewed. The schedule indicated the description of different sampling areas and the dates of sampling, in accordance with the respective SOP.

Environmental monitoring was performed in accordance with the applicable SOP. A selection list of active air sampling locations and a list of passive air sampling locations (settle plates) in Formulation Block-01 were available. Records related to the Blender-1 area, including testing and results for the period of June 2024, were available and reviewed.

Standard Operating Procedures governed all QC activities, including sampling, testing, release, and retention of samples. The following SOPs were reviewed:
- SOP for Analytical Method Transfer; the analytical methods used for QC testing of the products were developed and validated by Desano Shanghai. The site, therefore, carried out method transfer verification. The scope of the method transfer was described in the SOP. Verification of dissolution testing for all three molecules was spot-checked.
- SOP for Sampling of Raw Materials (API & Excipients).

QC personnel were qualified, and training was provided on GMP, safety, and analytical techniques. Reference standards, working standards, and reagents were controlled in accordance with defined procedures, and proper documentation was maintained to ensure traceability.

Testing records, certificates of analysis, and other QC documents were maintained in accordance with data integrity principles and were readily retrievable. Laboratory equipment was qualified and calibrated according to the established schedule.

An OOS logbook was available. OOS results were handled in accordance with the respective SOP. The SOP was discussed and found satisfactory. If the OOS investigation was inconclusive, the case proceeded to Phase II, during which manufacturing processes were also investigated in accordance with SOP for Handling of Investigations.

Retention samples of each finished product batch were stored for at least one year beyond the expiry date, in final packaging and under the recommended conditions. However, in the absence of commercial batch production, the retention of exhibition batches and materials used in production

was inspected. In the same room, the company also kept reference samples from the starting and packaging materials.

The issuance of templates used for different activities within the QC laboratory was described in the respective SOP. The templates were provided as tear-off sheets in respective logbooks, each bearing serial numbers. The logbooks were issued, and the details of issuance were recorded in the logbook for format/register/document issuance and retrieval, together with reconciliation records. Each logbook was closed at the end of the year, and a new logbook was issued at the beginning of the following year.

The sampling and analytical data sheet for a selected batch took place on 25 June 2024, and the sample was tested on 24 July 2024. Altogether, three exhibition batches were produced in June 2024, and the following documentation was reviewed:

- Sample test request form.
- FPP release analytical method, including microbial enumeration test and tests for specified microorganisms.
- Dissolution testing – spot-checked, including results and raw data (validated Excel sheets) and analytical sheets.
- Assay testing – spot-checked, including results (validated Excel sheets) and analytical sheets.
- Checklist for chromatographic analysis of related substances – spot-checked.
- System suitability run for related substances and respective checklist – system suitability was always part of the analytical run, with RSD for six standard replicates used to verify suitability.
- Random check of the audit trail of a selected HPLC system, together with verification of access rights for different roles and functionality of the audit trail.

The list of authorized personnel was not displayed at the entrance of restricted areas, such as the retention sample storage. However, access was controlled through biometric means, and a logbook was maintained for this purpose.

Observations related to the QCL and its activities were addressed in the respective CAPA plan.

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

Part 3	**Conclusion – Inspection outcome**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***Desano Pharmaceuticals Private Limited***, located at ***Plot No.600 - 612, Harohalli KIADB Industrial Area, 3rd Phase, Bannikuppe Village, Kanakapura Taluk, Ramanagara District, Bengaluru, Karnataka 562112; 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 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.
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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.
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   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
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   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.
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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
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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.
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