

TMDA/DMD/MCIE/F/001  
REV.# 01



THE UNITED REPUBLIC OF TANZANIA  
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

JODAS EXPOIM PVT LTD, TELANGANA, INDIA  
PUBLIC GMP INSPECTION REPORT

Date: March, 2025



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### General information about the company

<b>Manufacturers details</b>	
Name of manufacturer	Jodas Expoim Pvt. Ltd
Corporate address of manufacturer	Plot No 55, Phase-III, Biotech Park, Karkapatla Village, Markook (Mandal), Siddipet (District), Telangana 502279, India. Tel: +91 8454 244600/601 Website: <a href="http://www.jodasexpoim.in">http://www.jodasexpoim.in</a>
<b>Inspected site</b>	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	General products liquid for injection (LVP and SVP) manufacturing block Oncology liquid for injection (SVP) and OSD (Tablets) manufacturing block
<b>Inspection details</b>	
Date of inspection	10 <sup>th</sup> & 11 <sup>th</sup> June, 2024
Type of inspection	GMP Pre-registration Inspection
<b>Introduction</b>	
General information about the company and site	Jodas Expoim Pvt Ltd was a private company established in the year 2006, the two blocks were commissioned in the year 2018 and hence it had 6 years of experience in the development, manufacture, and marketing of finished human pharmaceutical products containing cephalosporins in the form of dry powder for injection in dedicated block, oncology products in the form of OSD (tablets) and liquids for injection (SVP) in dedicated block and general products in the form of liquids for injections (LVP and SVP) in dedicated block.
History	The facility was inspected and licensed by the following Local National Regulatory



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	<p>Authorities;</p> <p>In 2021 this site was inspected and approved by Ministry of Industry and Trade of the Russian Federation</p> <p>In 2023 this site was inspected and approved by National Authority of Medicines and Health Products of Portugal</p> <p>In 2024 this site was inspected and approved by Drugs Control Administration Government of Telangana State</p>
<b>Brief report of the activities undertaken</b>	
Areas inspected	<p>Areas inspected include external surroundings, utilities, warehouses, manufacturing areas and quality control laboratory</p> <p>Other areas include, qualification and validation, handling complaints, vendor evaluation, contract agreements, premise layout, sanitation and hygiene, personnel, equipment, and documentation</p>
Restrictions	GMP inspection was restricted to production line which manufactured registered products - manufacturing of general products in the form of liquid for injection (LVP and SVP) and Oncology liquid for injection (SVP) and OSD (Tablets).
Out of scope	Production lines whose products are neither applied for registration nor registered in the country
Production lines inspected by TMDA	General products in the form of liquid for injection (LVP and SVP) and Oncology liquid for injection (SVP) and OSD (Tablets).
<b>Abbreviations</b>	<b>Meaning</b>
AHUs	Air Handling Units
API	Active Pharmaceutical Ingredient
AVUs	Air Ventilation Units
BMR	Batch Manufacturing Record
BMS	Building Management Systems
BOD	Biochemical Oxygen Demand
BIBO	Bag-In/Bag-Out



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BPR	Batch Packaging Record
CAPA	Corrective action and Preventive Action
CIP	Cleaning In Place
EDI	Electrodeionization
EMS	Environmental Monitoring Systems
ERP	Enterprise Resource Planning
FDA	Food and Drug Authority
FPP	Finished Pharmaceutical Products
FTIR	Fourier Transform Infrared Spectroscopy
GC	Gas Chromatography
GMP	Good Manufacturing Practice
HEPA	high-efficiency particulate air
HPLC	High Performance Liquid Chromatography
HVAC	Heating, Ventilation and Air Conditioning
LAF	Laminar Air Flow
NMRA	National Medicine Regulatory Authority
OOS	Out of Specification
OOT	Out of Trend
OSD	Oral Solid Dosage form
PLC	Programmable Logic Controller
PQR	Product Quality Review
QA	Quality Assurance
QC	Quality Control
QRB	Quality review Board
SCADA	Supervisory Control and Data Acquisition
SOP	Standard Operating Procedure
TOC	Total Organic Carbon
WHO TRS	World Health Organization Technical Series Report
WTP	Water Treatment Plant

### Part 2: Brief summary of the findings and comments

#### 1. Personnel

The manufacturer had sufficient number of technical staff with necessary qualifications and experience to carry out the tasks assigned. Personnel met were knowledgeable about principles of GMP which proved that they received basic and on job training on principles of GMP relevant to their needs and in accordance with GMP training schedule in place.

Effective Date: 01/11/2022



The organizational chart was reviewed whereby key responsibilities were held by permanent staff, head of production unit and quality unit were independent of each other.

There was a procedure in place for medical checkup. Pre-employment health check was done for new employee while all other personnel were checked annually. Adequate measures were taken for personnel hygiene and personnel were observed properly dressed with neat and clean gowns, gloves and masks.

## **2. Premises**

### **a. Layout and Design**

The plant was designed with three dedicated manufacturing blocks to manufacture oncology, general injectables, and cephalosporins products, the latter was not in the scope of this inspection. Each block was constructed mainly by use of brick and mortar, painted with a non-flaking paint. The ceiling and walls were made of concrete base and painted with oil paints which allowed easy cleaning and disinfection. The flooring material was of epoxy paint for easy cleaning and to avoid recesses for contamination.

The facilities were provided with changing rooms for both male and female staff. The change areas were designed to provide separate man and material movement to production areas. In addition, airlocks for entries of equipment, materials, and personnel to clean areas were provided.

### **b. Sanitation and Hygiene**

Premises and equipment were generally cleaned according to established procedures described in SOPs. The facility had changing rooms and toilets equipped with washing basins and sanitization points. The toilets had no direct communications with production and storage areas, and change rooms were well-ventilated, maintained, and had documented procedures with pictorial presentations for gowning, degowning, hand washing, and dress code. Cleaning records for manufacturing rooms and equipment were in place and some were verified.

Premises and equipment were cleaned frequently by approved documented procedures, and records were maintained.

## **3. Production**

Generally, production operations followed defined procedure and production plan in place, BMR and BPR were maintained, properly filled on completion of each



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manufacturing and packaging stage. Weighing and measuring devices were of suitable accuracy for the intended use and records were maintained in respective logbooks.

Temperature, relative humidity and differential pressures were monitored in the production areas and the same were observed to be within limits and records were available. Environmental monitoring was performed during filling using settle plates and particulate counters and the records were verified during document review. Punches and dies were stored in separate room, usage and cleaning records were maintained.

### a. General block - Liquid Injections (LVP and SVP) Production Line

Manufacturing of liquid injectables in the form of LVP and SVP vials was performed in a dedicated production line. Most of the operations were carried out in a closed system, which involved component preparations, product preparations, and product filling. There were two distinct areas for component preparations and filling, followed by terminal sterilization of the product. Pressure differentials of the component preparation room were negative relative to the filling room hence minimizing the entrance of undue contaminants.

A separate staging room for dispensed raw materials and components such as vials, stoppers, and crimps of a batch were provided. Containers/vessels were sanitized by IPA 70% for surface microbial disinfection of containers before being transferred via dynamic pass box to the component preparation area

Vials were washed using automatic washing machine which used purified water, recirculated water, and WFI at NLT 80°C followed by drying using compressed air then sterilization. Depyrogenation of cleaned vials at 320± 5°C tunnel was performed.

Prepared batch solutions were filtered through a PES filter (Polyethylene Sulfonate-Hydrophilic filter), and records of bubble test before and after filtration for filter integrity test were verified. After Batch solutions filtration by PES filter, the filtered solution was stored in a sterile bulk solutions tank, samples were taken for assay and pH checks. The product was then terminally sterilized. IPQC tests such as clarity, conductivity, TOC, and WFI endotoxins were performed.

### b. Oncology Tablet Production Line

Production areas for OSD (tablets) comprised suitably designed equipment for the production of oral solid dosage was in place. Equipment used for Sampling, Dispensing, Mixing, Blending, Drying, Compression, and Coating were equipped with barrier isolators designed to segregate operators from the product to avoid contamination.



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To contain the contaminants from low to higher grade areas, personnel were entered into the production areas through primary and secondary changes via airlocks while the raw materials were through pass boxes of the desired type.

The tablets were manufactured by dry granulation that was divided into different individual unit operations such as dispensing, sifting, dry mixing, granulation, wet mixing, drying, milling, lubrication, compression, coating, blister packaging, and secondary packing.

After dispensing raw materials, weights were verified by the production department in the day store room. Line clearance was performed before the beginning of unit operation.

### **c. Oncology Liquid Injection Line**

Manufacturing operations were carried out in a closed system. Manufacturing involved component preparations, product preparations, and product filling. There were two distinct areas for component preparations and filling, followed by terminal sterilization of the product. Pressure differentials of the component preparation room were negative relative to the filling room hence minimizing the entrance of undue contaminants. To contain the contaminant from low to higher grade areas, personnel were entered into the production areas through primary and secondary changes via airlocks while the raw materials were through pass boxes of the desired type.

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### 4. Quality Control

The quality control laboratory was divided into chemical section, primary packaging section, and microbiological section. Microbiological section had separated AHUs to supply filtered air into the rooms.

The QC laboratory was responsible for analysis and release of dosage forms, active ingredients, raw materials, intermediates, packing materials and environmental monitoring. The procedures and logbooks, calibrations, daily weight checks temperature and humidity monitoring were in place.

Raw and packaging materials and finished goods were tested as per specifications using validated analytical methods. All incoming materials were sampled according to predefined sampling plan and given unique analytical reference number.

The facility used primary and working standards with specified shelf life which were stored in a temperature-controlled refrigerator, were temperature and relative humidity of the same were monitored. The working standards were prepared from approved lot of the raw materials and qualified against the pharmacopeia primary reference standards (USP, BP and EP). The register for the use of reference standard was maintained. The list of primary standards was maintained and their validity in the respective on web-catalogues was confirmed.

Retention samples were kept in a secured and temperature-controlled room, retention sample register and samples of each batch finished product produced were kept with double quantity of full testing. Annual check for the sample was performed according to the company procedures. The facility had five (5) walk-in stability chambers, of which one stability chambers was set at long-term conditions ( $30 \pm 2^{\circ}\text{C}$  /  $75 \pm 5\%$  RH).

Reagent and solutions were handled as per procedure with detailed information regarding to preparation and standardization of volumetric solutions, all the glassware used in the facility were class A. Reagents and solutions were labeled with solution/reagent name and information on shelf life, list of QC reagents and solutions was well maintained.

### 5. Equipment

The equipment in all manufacturing lines was well designed and located to suit the operations and permit for effective cleaning. Manufacturing equipment were qualified, requalification, revalidation and equipment maintenance schedules were in place and adhered to so as to ensure that all equipment function properly and meet their intended



purposes. All equipment were affixed with both calibrations, maintenance and machine status label

Methods of cleaning were validated. Swabs and a final rinse were used for collection of samples for residual and detergent removal. Samples were tested for chemicals and microorganisms.

### **6. Purified water System**

Each block had its own WTP. Purified water was used as a source for WFI generation unit. Production involved RO treatment which produced purified water and then distilled to produce WFI. WFI was stored into 316SS WFI tank. WFI from the storage tank was distributed to various user points

Sampling points were well identified in the entire system as per qualification reports. Testing parameters such as pH, conductivity, particulate and microbial contaminations, and TOC were conducted for water quality analysis, and records were maintained.

### **7. Heating, Ventilation and Air Conditioning**

Each block separate floor housed the air handling units (AHUs). AHUs for the general block injectables were designed with 10  $\mu\text{m}$ , 5  $\mu\text{m}$ , and 3  $\mu\text{m}$  filters, and the HEPA filter of 0.3  $\mu\text{m}$  (micro glass fiber and filter media: synthetic non-woven materials) mounted at the terminal end and those for the oncology block had additional BIBO filters mounted in the plenum.

There was a 10% fresh air supply and 90% air recirculation, this design was justified by a risk assessment and CCS. Processing areas, corridors, primary packaging areas, dispensing, and sampling areas of the store, are of class A. Air supplied to all critical areas was filtered through HEPA filters of 0.3 $\mu\text{m}$  pore size with 99.97% efficiency. In other non-critical areas, air was filtered through 3.0  $\mu\text{m}$  filters (raw material, quality control & packing areas) and 5  $\mu\text{m}$  filters (finished product warehouse). The microbiological testing room was provided with separate AHU with terminal HEPA filters of 0.3  $\mu\text{m}$  pore size with 99.97% efficiency.

Preventive maintenance plans for the entire unit were available and some were reviewed by inspectors as spot checks and were found acceptable.

### **8. Document Review**

Documentation was designed, prepared, reviewed and distributed to users according to procedure for preparation, issuance, recording, retrieval, storage and destruction of



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documents. The documents related to assurance of quality and safety of pharmaceutical products being manufactured, were prepared by the quality management department, followed and controlled. Records were reviewed and accepted.

### Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection **Jodas Expoim Pvt. Plot No 55, Phase-III, Biotech Park, Karkapatla Village, Markook (Mandal), Siddipet (District), Telangana 502279, India** is considered to be operating at an acceptable level of compliance with with TMDA Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, 2023 for manufacturing of general products in the form of liquid for injection (LVP and SVP) and oncology products in form liquid for injection (SVP) and OSD (Tablets).

This TPIR will remain valid until 10<sup>th</sup> June, 2027, provided that the facility will remain compliant following any inspections conducted in the period.

### Part 4: References

1. TMDA, (2003)., Tanzania Medicines and Medical Devices Act, Cap 219, Tanzania Medicines and Medical Devices Authority, Government Printers, Dar es Salaam, Tanzania
2. TMDA (2023)., Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Dar es Salaam
3. TMDA, (2018)., Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations GN No. 295. Tanzania Medicines and Medical Devices Authority. Government Printer, Dar es Salaam, Tanzania
4. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority Dar-es-Salaam, Tanzania.
5. SMF, (2023)., Jodas Expoim Private Limited,
6. Jodas Expoim Private Limited, Dossiers