THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

(EAST AFRICAN (INDIA) OVERSEAS, DEHRADUN, UTTARAKHAND, INDIA)
PUBLIC GMP INSPECTION REPORT

4th March, 2025

General information about the company

Manufacturers details	
Name of manufacturer	East African (India) Overseas
Corporate address of manufacturer	Same as below
Inspected site	
Name & address of inspected manufacturing site if different from that given above	East African (India) Overseas Plot No.1,8 & 8A, Pharmacity, Selaqui, Dehradun, Uttarakhand, India
Unit/ block/ workshop number	Block A, B and C
Inspection details	
Date of inspection	03rd & 4th October, 2025
Type of inspection	Re inspection for block A& B Pre-registration inspection for block C
Introduction	
General information about the company and site	The facility was engaged in manufacturing, packaging and quality control of: - • General and Herbal Formulations in form of tablets, capsules, injections (powder and liquid), syrups, ophthalmic and external preparations. • Cephalosporin in form of tablets, capsules, injections (powder and liquid) and syrups • Penicillin in form of tablets, capsules, injections (powder and liquid) and syrups
History	East African (India) overseas was established in the year 1980. The firm was licensed by the Drugs Controller, Dehradun, Uttarakhand with license no. 70/UA/2009, 94/UA/SC/P-2009 to manufacture for sale pharmaceutical dosage forms of tablets, capsules, injection - liquid &

	dry powder, ophthalmic and external preparations.
Brief report of the activities undertaken	
Areas inspected	Areas inspected included the external surroundings, raw materials warehouse, manufacturing and packaging areas, Quality control laboratory and utilities (Water Treatment Plant, HVAC system, Compressed air and Effluent Treatment Plant) and finished goods warehouses.
Restrictions	None
Out of scope	None
Production lines inspected by TMDA	• General and Herbal Formulations: -Tablets, Capsules, injections (powder and liquid), syrups, ophthalmic and external preparations lines. • Cephalosporin: -Tablets, capsules, injections (powder and liquid) and syrups lines • Penicillin -Tablets, Capsules, injections (powder and liquid) and syrups lines
Abbreviations	**Meaning**
HVAC System	Heating, Ventilation and Air Conditioning System
SOP	Standard Operating Procedures
SS	Stainless Steel
AHUs	Air Handling Units

Part 2: Brief summary of the findings and comments
(Indicate summary of observations made during inspection of the manufacturing facility)

1. Personnel

The facility had sufficient number of qualified and experienced personnel to carry out activities at the site. Review of qualifications of key personnel along with those stationed at key areas was performed during inspection. Documents such as appointment letters and job descriptions for key personnel were reviewed. Medical examination was carried out every year and pre-employment. Training was provided to all employees as per SOP in place.

2. Premises

a. Layout and Design

The facility was located, designed, constructed, adopted and maintained to suit the operations carried out. Interior surfaces (walls and floors) of storage and production areas were constructed with suitable materials that permit effective cleaning and sanitation. The layout of the facility allowed for the maintenance of major components. from the service corridors. The entire manufacturing and warehouse areas of all blocks were designed for ventilation and filtered air was supplied through air handling units installed. All areas were provided with adequate working space for working and logical placement of equipment and materials to avoid mix us and cross contamination. The buildings were provided with change rooms with proper gowning instructions.

b. Sanitation and Hygiene

There were written procedures for cleaning of manufacturing areas and equipment. All areas were cleaned daily as per respective SOP. During inspection, cleaning validation protocols and reports were reviewed and found satisfactory.

3. Production

The facility had 3 production blocks which include Block A for non-beta lactam and herbal products, block B for production of Cephalosporin and block C for production of Penicillin.

a. Production in Block A

The block was dedicated for production of General formulations in form of tablets, capsules, injections (dry powder and liquids), ophthalmic and external preparations. Manufacturing processes were initiated in accordance with instructions in the BMR.

Critical process parameters and critical quality attributes were monitored during production.

b. Production in Block B- Cephalosporins

This block was dedicated for production of beta lactam (Cephalosporins) in form of tablets, capsules, dry powder for injections and dry syrup. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production

c. Production in Block C- Penicillins

This block was dedicated for production of beta lactam (Penicillin formulations) in form of tablets, capsules and dry powder. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production.

Generally, in all production blocks measures to prevent cross contamination and mix ups were in place and use of status labelling of materials and products, use of validated clean procedures, use of segregated production cubicles, positive pressure was maintained in corridors with respect to manufacturing cubicles, monitoring of pressure differentials, temperature and relative humidity, use of primary, secondary and tertiary gowning procedures before going to production areas, instituting campaign manufacturing, use of sealed double polyethylene bags and HDPE containers for storage of dispensed and in process materials with proper labelling and identification, use of dedicated sampling and dispensing booth for APIs, excipients and packaging materials, proper segregation of packaging lines and performing line clearance before starting manufacturing and packaging operations were in place. Samples were received, registered and distributed to analysts through Laboratory Information Management System (LIMS). Testing was conducted as per the specifications using validated analytical procedures

4. Quality Control

There were two separate laboratories where one served Block A and B and another one for Block C. The laboratories were divided into instruments room, wet chemistry, stability section and Microbiological laboratory. Raw materials, packaging materials, in process, finished products and stability samples were tested in the laboratory. Testing was conducted as per the specifications using validated analytical procedures.
The laboratory was equipped with adequate equipment for carrying out relevant tests for all products. A list of materials used as reference standards was prepared. Most of the reference solutions were prepared within the facility and evaluated against the

Pharmacopoeia primary reference standards (USP, BP). Primary and Working standards were stored in refrigerator where temperature was monitored. All raw data obtained from various analyses were recorded in the approved analytical work report which were then transferred to an electronic software maintained by the facility for the generation of certificate of analysis. Class A glass wares were used in preparations of different solutions and reagents. Reagents, prepared test and volumetric solutions were handled and labelled according to written procedures.

5. Equipment

Critical manufacturing equipment were qualified, the measuring devices calibrated in accordance with Validation Master Plan. There was adequate number of equipment with were orderly placed in all production areas. Access control, alarm system and audit trail of each equipment was reviewed Equipment cleaning was performed as per SOPs. Production equipment were maintained inhouse by qualified maintenance staff as per preventive maintenance schedule.

6. Purified water System

There was separate Water Treatment plant for each block. The source of raw water was bore well. Raw water was treated to generate portable water and then to double pass reverse osmosis system. The purification system was also comprised of UV lights whereby light intensity was monitored and recorded. Th e generated purified water was stored in SS316L storage tanks and distributed through SS pipes under UV sterilization and continuous loop system circulation. Purified water was used as starting material for production of Water for injection. Sampling points were identified/labelled. The system was cleaned, sanitized and maintained as per schedule and records were verified. Moreover, the system was validated and proved to consistently produce water of desired specifications.

7. Heating, Ventilation and Air Conditioning

Each production block had dedicated HVAC system which were qualified. Installed AHUs were capable of supplying filtered air into various manufacturing rooms. AHU's were clearly labelled to indicate the supplied rooms and direction of airflow. Maintenance and servicing of AHUs were done by full time employed and qualified persons according to SOP. Magnehelic pressure gauges were installed across filters of AHUs to measure pressure differential and assurance of filter integrity.

8. Document Review

The facility had Standard Operating Procedures for all activities performed. Various documents were prepared, authorized and distributed for use as per the mother SOP. Various records were produced and maintained as per SOP. During inspection, several documents were reviewed including records and were found to be appropriately prepared, maintained and stored in accordance to the SOP.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection, **East African (India) Overseas, Plot No. 1,8 & 8A, Pharmacity, Selaqui, Dehradun, Uttarakhand, India** was considered to be operating at **an acceptable** level of compliance with TMDA GMP Guidelines for Human Medicines for the production of **Block A (for manufacturing of General and Herbal Formulations in form of tablets, capsules, injections (powder and liquid), syrups, ophthalmic and external preparations), Block B (for manufacturing of Cephalosporins in form of tablets, capsules, injections (powder and liquid) and syrups), Block C (manufacturing of Penicillins in tablets, capsules, injections (powder and Liquid) and syrups).**

This report shall be invalid if the forms and operations herewith are changed or if the site is no longer considered to in compliance with current GMP requirements.

Part 4: References

1. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Tanzania.

2. Site Master File -EAR-SMF-05-05.

3. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania.

4. Tanzania Medicines and Medical Devices Act, Cap 219.

5. TMDA, Good Manufacturing Practices Enforcement Regulations (2018), Tanzania Medicines and Medical Devices, Dar-es-Salaam, Tanzania.