



THE UNITED REPUBLIC OF TANZANIA  
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

DEVA HOLDINGS A.S., CERKEZKOY-I, TEKIRDAÖ, TÜRKIYE  
PUBLIC GMP INSPECTION REPORT

January, 2026



## TMDA PUBLIC INSPECTION REPORT



TMDA/DMC/MCIE/F/001  
Rev #:01  
Page 1 of 7

### Part 1: General information about the company

| <b>Manufacturers details</b>   |  |
|--|--|
| Name of manufacturer   | Deva Holdings AS — Cerkezko -1   |
| Corporate address of the manufacturer  | Ataturk Cad. No. 32, 59510 Kapaklı — Tekirdag, Türkiye<br>Telephone number: +90 282 735 20 00/ 2010<br>Website/email address: <a href="mailto:info@deva.com.tr">info@deva.com.tr</a><br><a href="http://www.deva.com.tr">www.deva.com.tr</a>   |
| <b>Inspected site</b>  |  |
| Name & address of inspected manufacturing site, if different from that given above | Same as above.   |
| Unit/ block/ workshop number   | N/A  |
| <b>Inspection details</b>  |  |
| Date of inspection   | 30 <sup>th</sup> September to 1 <sup>st</sup> October 2024   |
| Type of inspection   | Routine inspection   |
| <b>Introduction</b>  |  |
| General information about the the company and site                                 | <p>Deva Holdings AS was established in 1958 by a group of medical professionals. In 2006, Deva facility was acquired by East Pharma and restructuring of the plant began in 2007 and completed in 2009.</p> <p>The company was engaged in the manufacturing of;</p> <ul style="list-style-type: none"><li>- general pharmaceutical products (tablets, capsules, oral liquids (syrup/suspension) and sterile injections.</li><li>- Penicillin products in form of dry powder for suspension, sterile powder for injection, tablets and capsules</li><li>- Cephalosporins in form of dry powder for suspension</li><li>- Hormones in form of solution for injection</li><li>- Inhalers</li></ul> |



# TMDA PUBLIC INSPECTION REPORT



TMDA/DMC/MCIE/F/001  
Rev #:01  
Page 2 of 7

|  |   |
|--|---|
|  |   |
| History  | The facility was inspected and approved by TMDA Turkish Ministry of health, EU and USFDA  |
| <b>Brief report of the activities undertaken</b> |   |
| Areas inspected                                  | Inspection focused on the following GMP systems; <ul style="list-style-type: none"><li>• Pharmaceutical Quality System</li><li>• Production System</li><li>• Facilities and Equipment System</li><li>• Laboratory Control System</li><li>• Material System</li><li>• Packaging and labelling System</li></ul> |
| Restrictions                                     | None  |
| Out of scope                                     | None  |
| Production lines inspected by TMDA               | The inspection covered manufacturing lines for; <ul style="list-style-type: none"><li>- Hormones (injection)</li><li>- General pharmaceuticals (sterile injection)</li><li>- Penicillin (oral syrups &amp; powder for injection)</li></ul>  |
| <b>Abbreviations</b>                             | <b>Meaning</b>  |
| AHU  | Air Handling Unit   |
| CAPA   | Corrective Actions and Preventive Actions   |
| GMP  | Good Manufacturing Practices  |
| HEPA   | High Efficiency Particulate Air   |
| HVAC   | Heating, Ventilation, and Air Conditioning  |
| QA   | Quality Assurance   |
| QC   | Quality Control   |
| SOP  | Standard Operating Procedure  |
| SS   | Stainless steel   |



## TMDA PUBLIC INSPECTION REPORT



TMDA/DMC/MCIE/F/001  
Rev #:01  
Page 3 of 7

|      |  |
|------|--|
| TMDA | Tanzania Medicines and Medical Devices Authority |
|------|--|

### Part 2: Summary of the findings and comments

#### 1. Personnel

The facility had a sufficient number of personnel with appropriate qualifications and experience to perform production and quality control activities.

Personnel were aware of the principles of GMP which proved that they were provided with basic principles of GMP training and on job training relevant to their needs. The procedure and selected records for some personnel were reviewed and found to meet requirements.

Personnel were medically examined at the time of joining the company and after every 3 years while on job. Records were verified and found in line with the requirements.

Moreover, personnel hygiene and hygienic practices were observed such that, in all areas personnel were observed wearing clean uniforms and maintain good hygienic practices. High levels of personnel hygiene was maintained to protect the personnel and the products.

#### 2. Premises

##### a. Layout and Design

The site had a total of 11 independent blocks of which 6 were used for manufacturing and 5 were used for utilities and administration.

Dedicated facilities were provided for API warehouses and production of general formulations, penicillin and hormones.

The outer structure was constructed with concrete cement and inside was finished with epoxy flooring, modular panels on walls and roofing.

The facility manufacturing areas were constructed using reinforced concrete cement and easy-to-clean epoxy flooring. Doors were double glazed. Smooth finish was provided between walls to walls and walls to roof and there were no cracks or crevices. Generally, all manufacturing areas for sterile and non-sterile products were arranged in



orderly manner to permit uni-directional flow of events from materials dispensing, manufacturing to secondary packaging to minimize possibility of mix ups and cross contamination.

**b. Sanitation and Hygiene**

Adequate change room with interlocking air locks were provided for personnels. Rodent traps were found placed in different positions to prevent them from entry to production and material warehouses. Gowning and degowning procedure along with pictorial diagrams were available in the change rooms and were properly followed. Processing rooms were observed clean and the same had minimum number of personnel to minimize the risk of cross contamination. Disinfectants were used in rotation basis to prevent microbial resistance.

**3. Production**

**i. Production Line – Oral solids**

Dedicated rooms for each manufacturing process were provided. Dedicated sampling and dispensing booth were also available. Temperature, relative humidity and pressure differentials were monitored and recorded. All compression machines were provided with online dust extractors and metal detectors to ensure tablets produced were polished and had no any foreign parts in it. Line clearance was performed as per procedures and records were verified in the reviewed BMR.



## TMDA PUBLIC INSPECTION REPORT



TMDA/DMC/MCIE/F/001  
Rev #:01  
Page 5 of 7

### ii. Production Line – Oral Liquids

The facility had two manufacturing suites for oral liquids products.

### iii. Production Line – Hormone

Classified rooms were provided. Ampoules were washed and sterilized before use. Solution preparation was done in Class C, filtration and filling in class A with background of class B. Visual inspection was done before final packaging. Isolators were provided for materials dispensing and processing of finished products.

### iv. Penicillin Productions

Dispensing of materials was done under LAF. Vials were washed and depyrogenated as per the requirement. Visual inspection and line clearance were also performed, records were verified in the BMRs.

Generally manufacturing processes were validated and manufacturing was performed as per the validated parameters. The facility was neither engaged in contract manufacturing nor reworking

## 4. Quality Control

The facility had a quality control (QC) laboratory which was separated from production areas.

The QC laboratory had sufficient number of trained personnel with appropriate qualifications and experience was responsible for analysis and release of dosage forms, active ingredients, raw materials, intermediates, packing materials and environmental monitoring.

Modern analytical instruments were available, the same were found qualified/calibrated. Accelerated and long-term stability studies were carried out based on the established protocol and stability results were maintained in the LIMS. Products were properly arranged in the chambers and were easily traceable.

Reference and working standards were properly stored and easily retrieved. Retained samples were observed to be stored at appropriate storage conditions according to the documented procedure in place and the room was well maintained for temperature and relative humidity.



## 5. Equipment

The manufacturing facility was provided with adequate equipment which were generally designed, constructed installed, located and maintained to fit the purposes of the operations to be carried out. The layout and design permitted effective cleaning thus preventing the risk of cross contamination build - up of dust or dirty. Calibration and preventive maintenance were performed according to the established schedules. Equipment was adequately cleaned and sanitized as per validated cleaning and available sanitization procedure; records were verified. Preventive maintenance, calibration and cleaning status labels were in place.

## 6. Water Treatment System

The water treatment plant, located on the floor of the facility, uses water from the city water supply for various activities. The water was treated by passing through sequence of filters, softener, RO, EDI then the PW was collected in the SS 316 tanks. PW was passed under UV lamp to the user points. WFI was generated passing PW under multicolumn distillation unit then later was collected in SS tank and then circulated under continuous loop. Periodic sanitization and preventive maintenance were performed as per procedure; records were in place. Online monitoring of the system, chemical and microbial tests were performed to ensure no contamination.

### Heating, Ventilation, and Air Conditioning

Each manufacturing block had dedicated HVAC system for supplying clean air to different processing areas from class A-D and controlled areas. Non-sterile areas were provided with class D while sterile areas were provided with class A to D. There were 35 AHUs which were provided with mixed air unit each cycle with 20% fresh air and 80% recycled air. Preventive maintenance, requalification and cleaning of filters were performed as per the procedure in place.

## 7. Document Review

The review of documents proved that, the company had a good documentation system as documents were designed, prepared as per the GMP requirements. The same were prepared, approved, signed and dated by appropriate responsible personnel and were distributed with care. Records were observed to be up to date, document review was done in timely manner as per the procedures. Electronic data management and processing system were password protected which restricted their usage and only authorized personnel were responsible for managing the system.



## TMDA PUBLIC INSPECTION REPORT



TMDA/DMC/MCIE/F/001  
Rev #:01  
Page 7 of 7

### Part 3: Conclusion

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 Part 2 and 3, Deva Holdings AS, Cerkezkoy - 1, Çerkezköy Organize Sanayi Bölgesi, Karaagaç Mah. Atatürk Cad. No. 32, 59510 Kapaklı — Tekirdag, Türkiye was considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines for Human Medicinal for manufacturing of general formulations in form of tablets, and syrup/suspension.

***This TPIR will remain valid for three (3) years from the date of approval for GMP compliance provided that the outcome of any inspection conducted during this period is positive.***

### Part 4: References

1. Tanzania Medicines and Medical Devices Act, Cap 219.
2. The Tanzania Medicines and Medical Devices (Good Manufacturing Practice Enforcement) Regulation, 2018.
3. The Tanzania Medicines and Medical Devices Authority Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 1st edition, April 2023.
4. TMDA Good manufacturing practices SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania.
5. Site Master File Document no. CK SMF 01.35 effective 07/12/2023.