

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



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GLOBAL NAPI PHARMACEUTICALS, 2ND INDUSTRIAL ZONE, 6TH OCTOBER CITY,
GIZA, EGYPT
PUBLIC GMP INSPECTION REPORT

March, 2025



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General information about the company

Manufacturers details	
Name of manufacturer	Global Napi Pharmaceuticals
Corporate address of manufacturer	2 nd Industrial zone, Plot 40, Street 18, 6 th of October, Giza, 12581, Giza, 12581, Egypt
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	Manufacturing Block
Inspection details	
Date of inspection	4 th -5 th February, 2024
Type of inspection	Routine Inspection
Introduction	
General information about the company and site	<p>Global Napi Pharmaceuticals was located at 2nd Industrial zone, Plot 40, Street 18, 6th of October, Giza, 12581 Egypt.</p> <p>The facility is engaged in the manufacturing of general oral solid formulations in form of tablets and capsules, oral solutions, general and corticosteroid semi-solid formulations such as creams, ointment and suppositories</p>
History	<p>The facility was licensed by EDA with license No. 618042702009075 issued on 4th June, 1997 for manufacturing, packaging and quality control of the following formulations;</p> <ol style="list-style-type: none">i. Oral Solids (Tablets, hard gelatin capsules, powder filled in sachets and bottles)ii. Oral Liquid (Syrup and Suspension)iii. Semi-solid therapeutic formulations (creams, ointments, gel and



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	suppositories). The facility was previously inspected by TMDA on 2 nd to 3 rd October, 2018 and complied with the minimum requirements of GMP. It held a valid GMP certificate number P-249/2023 issued on 14th March 2023 by the Egyptian Drugs Authority.
Brief report of the activities undertaken	
Areas inspected	The inspection covered various quality elements of GMP to include documentation control, personnel, change control, annual product review, self-inspection and suppliers qualification, complaints, product recall, deviation management, management review meetings, product release, stability programs, qualifications, validations, quality risk management, production, reprocessing/reworking, sanitation and hygiene, equipment maintenance and calibration, environmental monitoring, utilities, water treatment plant, quality control, raw materials management, packaging and labelling
Restrictions	
Out of scope	Production lines for products that have not been applied for registration in Tanzania
Production lines inspected by TMDA	The inspection was based on the General OSD (Tablets and Capsules), oral solutions and creams
Abbreviations	Meaning
AHU	Air Handling Units
BMR	Batch Manufacturing Record
EDA	Egyptian Drug Authority
GMP	Good manufacturing Practices
GNP	Global Napi Pharmaceuticals
HVAC	Heat-Ventilation and Air Conditioning
OSD	Oral Solid Dosage Form
PW	Purified water
QA	Quality assurance

Effective Date: 01/11/2022



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SOP

Standard Operating Procedure

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had a total of 603 personnel to cover different activities at the facility to include; production, quality unit, warehouse and engineering. They had qualification and experience necessary to execute their duties as required by GMP. Responsibilities of all personnel were well described in their job descriptions.

Heads of quality assurance and production were independent from each other as evidenced in the company's organizational chart. Personnel capacity was built and maintained through trainings provided to all the personnel at the facility at time of joining and at regular interval thereafter as per yearly training program.

Medical Examination was performed to all personnel at time of recruitment and at pre-determined interval for various occupation. Personnel exposed to hazard materials were additionally subjected to chest X-rays and pulmonary function tests every six months.

2. Premises

a. Layout and Design

The facility was designed in such a way that, arrangement of the various rooms allowed logical flow of production activities in a unidirectional mode. Walls and floors were smooth with covings between walls to floor, wall to ceiling as well as wall-to wall. The warehouse for storage of raw materials and finished goods was electronically managed and had adequate space. Change rooms were provided for personnel entering production areas to prevent contamination.

b. Sanitation and Hygiene

Adequate sanitation was observed at the facility. Production areas were cleaned at regular frequency and after production as required by the procedure and supported by cleaning records in the coating room from 26th September, 2023 to 4th February, 2024. Gowning procedures were observed by personnel before entering production areas. There were primary gowning and secondary gowning before entry to production areas (Class D).



3. Production

Production records were maintained in BMRs which were verified during the inspection. Critical process parameters were monitored as evidenced for the coating process of Cobal F (Mecopolamine+ Folic Acid) and compression of Pres 10mg and Glaryl 4mg tablets which were ongoing. In-process checks were performed at regular intervals and recorded in the BMR as verified for Glaryl 4mg tablets which were checked for average weight every 30 minutes and control charts developed to provide assurance that the compression process remained in the controlled state. Production of oral liquids was also found to comply with the minimum requirements. No issues were observed during inspection.

4. Quality Control

Quality control laboratory was equipped with adequate, qualified, calibrated instruments and equipment as supported by the records for calibration of Stability chamber (4) which was calibrated on 2nd January, 2024 as per the annual calibration plan. Calibration Certificate No. T/2024/334 RE issued 10th January, 2024 was also verified. Current specifications were used as verified for the specifications for Lonorxicam 4mg film coated tablets. Test methods used for analysis of products were validated and/ or verified depending on whether the method is compendial or in-house. All Out of specification results were investigated and lot rejected for confirmed OOS.

The facility had Reference standards for use in analytical testing. During inspection, Reference standard for Desloratadine was verified along with the respective working standard which was qualified by the Egyptian Drug Authority (EDA). Reagents and Volumetric solutions were well managed as per procedures. Records for preparation and standardization of volumetric solutions were verified and no issue was observed. Glassware used in the facility were class A as verified upon review of respective certificates of analysis.

Retained samples were stored in the retained sample room where environmental conditions were monitored. Temperature and relative humidity for the retained sample room were monitored as evidenced in Log book No. F/SQC4077/02 in which records from 18th October, 2023 to 4th February, 2024 were reviewed.

The facility was contracting out some tests to include identification tests for Biological Indicators and pure and fresh colony of viable counts (Environment and monitoring samples and water analysis). These were contracted out to (Centre of Scientific Excellence for Food Research and Analysis (cSERRA), Giza, Egypt. Valid contract was availed.



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5. Equipment

Equipment and utilities were maintained as per procedure No. PEN04:17 Effective from 12th November, 2023. Maintenance of equipment was done weekly for AHUs. Maintenance Logbook F/SUS 510/01 was reviewed and verified that maintenance was performed as per schedule. Utility calibration plan for 2023 was followed.

6. Purified water System

The water treatment plant had a capacity of 2.4m³/hr. Raw water was obtained from municipal water supply. Series of treatment included chlorination, filtration by sand filter, carbon filter, double softeners before storage into the soft water storage tank. Then water was passing through two (2) stage RO and sanitized by UV before supply to the user points. Online monitoring of flow rate, pressure and conductivity was performed during purification process. PW storage tank and distribution loop were sanitized by hot water at 85°C for 30 minutes once every two weeks. Records were maintained and reviewed. Water Treatment Plant was qualified and annual water review was performed.

7. Heating, Ventilation and Air Conditioning

The facility had a total of 34 AHUs to supply filtered air to various areas in the plant. In solid manufacturing & primary packaging areas, all the processing rooms were negative pressurized relative to the department corridor. In the semi-solids & liquid manufacturing areas, all rooms were positive pressurized relative to department corridor. Air was supplied through HEPA filters, however some minor issues related to performance of HVAC were observed during inspection.

8. Document Review

Documents used in the facility were controlled with revision number, date and approval signatures. Documents reviewed were found prepared, reviewed, authorized, distributed and maintained as per respective procedures, they were also distributed to vantage areas.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed Global Napi Pharmaceuticals, 2nd Industrial zone, Plot 40, Street 18, 6th of October, Giza, 1258, Cairo, Egypt was considered to be operating at an acceptable level of compliance with TMDA GMP guidelines, 2023 for the manufacturing of General Oral Solid Dosage Forms (Tablets and Capsules), General Oral Solutions and



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Suspensions, General and Corticosteroids Semi-solid therapeutic formulations (Creams, lotions, ointment and suppositories)

This report shall be valid for three (3) years from the date of approval unless forms and operations herewith are changed or the site is no longer considered to be in compliance with current GMP requirements. (State conclusion made based on inspection and validity period for compliance of the facility)

Part 4: References

1. Global Napi Pharmaceuticals GMP report
2. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition
3. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority Dar-es-Salaam, Tanzania. GMP Inspection Report forms No. TMDA/DMC/MCIE/F/036 Rev #: 02
4. TMDA (2019) Tanzania Medicines and Medical Devices Act, Cap 219
5. SMF - Ver. 17,2023
6. TMDA (2018) Good Manufacturing Practices Enforcement Regulations, GN 295