THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA
Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

UTOPIA PHARMACEUTICALS, 10TH OF RAMADAN - SHARKIA, EGYPT
PUBLIC GMP INSPECTION REPORT

March, 2025

General information about the company

Manufacturers details	
Name of manufacturer	Utopia Pharmaceuticals
Corporate address of manufacturer	Plot No. (2) Industrial Zone (A7)-Formerly Zizinia, Cairo-Ismailia Road - 10th of Ramadan-Sharkia
Inspected site	Ramadan- sharkia, Egypt
Name & address of inspected manufacturing site if different from that given above	Plot No. (2) Industrial Zone (A7)-Formerly Zizinia – 11868, Cairo-Ismailia Road - 10th of Ramadan-Sharkia Tel: (+2) 01150949999 Website: www.utopiapharma.com Email: utopiafactory@utopiapharma.com
Unit/ block/ workshop number	Manufacturing block for general pharmaceutical OSD for human use (Tablets and capsules, powder sachets oral liquid and dry powder for suspension)
Inspection details	
Date of inspection	28th -29th January, 2024
Type of inspection	GMP Pre-registration Inspection
Introduction	
General information about the company and site	Utopia Pharmaceuticals Limited was established in 2007 as a pharmaceutical distribution company before venturing into manufacturing business.
History	The facility was inspected and licensed by Egyptian Drug Regulatory Authority (EDA) in 2023 for OSD (Tablets and Capsules), liquid and dry syrup, non-effervescent powders filled in sachets
Brief report of the activities undertaken	
Areas inspected	Areas inspected include external surroundings,

	utilities, warehouses, manufacturing areas and quality control laboratory Other areas include, qualification and validation, handling complaints, vendor evaluation, contract agreements, premise layout, sanitation and hygiene, personnel, equipment, and documentation
Restrictions	GMP inspection was restricted to production line which manufactured registered products - general pharmaceuticals OSD for human use inform of (tablets and capsules), oral liquid and Oral dry powder in sachets and jar/bottle
Out of scope	Production lines whose products are neither applied for registration nor registered in the country
Production lines inspected by TMDA	General pharmaceuticals OSD for human use inform of (tablets and capsules), oral liquid and Oral dry powder in sachets and jar/bottle
Abbreviations	**Meaning**
AHUs	Air Handling Units
API	Active Pharmaceutical Ingredient
AVUs	Air Ventilation Units
BMR	Batch Manufacturing Record
BMS	Building Management Systems
BOD	Biochemical Oxygen Demand
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. 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**

Facility was designed to provide a logical flow of materials and segregated movement of personnel working in production, packing, QC and maintenance areas. There were four (4) buildings; Administration building, production building, warehouse and utilities and engineering building. The production building housed production areas, water station, AHUs and laboratories while utilities and engineering building housed water storage tanks, chillers, steam boilers and hot water skid.

The buildings were constructed using concrete with reinforced cement whereas the walls and ceilings in all production areas were painted with easy-to-clean epoxy paints. Sharp corners were avoided by the use of epoxy coving at the junction of ceiling–wall, wall-wall and wall-floor to minimize dust deposition and microbial growth, lights were flushed with ceiling. Air supply diffusers were placed on the ceiling and return risers were placed at the bottom of the walls. Production and storage areas were provided with adequate working space for orderly and logical placement of equipment and materials to avoid mix-ups and cross-contamination.

b. Sanitation and Hygiene

Personal hygiene at the facility was considered appropriate with respect to the manufacturing and packaging operations carried out, and in line with the GMP guidelines. There were procedures and pictorial illustrations in place for gowning on entry and exit to and from manufacturing area and medical health check procedure in place for occupational health of all employees and casual workers.

Validation of cleaning and sanitation procedure was conducted to assure that the procedure for cleaning and sanitation for processing machines, equipment, production rooms including processing and packaging area are consistency in line with the defined acceptance level of remainder active ingredients, detergent and microbiology.

3. Production

Generally, production operations followed defined procedure and production plan in place, BMR and BPR were maintained, properly filled on completion of each 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 area and the same were observed to be within limits and records were availed. 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. Oral Liquid production line

Dispensed raw materials were transferred to manufacturing area where manufacturing tanks were stationed, sugar was prepared in the sugar manufacturing tank, filtered and then transferred to manufacturing vessel. Other ingredients including active raw materials were mixed, filtered and then transferred to the manufacturing tank for mixing. Then product was filtered and transferred to the storage vessel where samples were sent to QC for analysis. After QC release, products were sent to filling room. Bottles

were decartoned, washed, dried and transferred to filling room. After filling and sealing, bottles were visually inspected and then labeled with online printing of batch numbers and secondary packaging.

b. Dry powder for suspension production line

For dry syrups, bottles were cleaned using compressed air then dispensed raw materials were blended followed by powder filling sealing and packaging. Moisture content was monitored in the powder production line.

c. Tablet production line

The manufacturing process involved dispensing of raw materials, verification of dispensed raw materials, sifting, granulation (dry or wet), drying and blending, compression, coating (where applicable), packaging, packing, sealing and boxing. Metal detectors and weight checkers were fitted at the capsule filling line. In process control test including moisture content, appearance and color, hardness, thickness, friability, disintegration were checked at start up and end of batch.

d. Capsule production line

The manufacturing process involved dispensing of raw materials, verification of dispensed raw materials, sifting, granulation (dry or wet), drying and blending followed by capsule filling, sealing and packaging. Metal detectors and weight checkers were fitted at the capsule filling line. In process checks and random samples of final product were analyzed based on the approved specification for the product and released according to laboratory test result then transferred to the finished goods warehouse.

4. Quality Control

The facility had a quality control (QC) laboratory which was separated from production areas. The QC laboratory was located in the administrative block and divided into different sections such as sample receiving area which was access-controlled, chemical laboratory, instrumentation rooms, microbiology section, stability room, and retained sample room. The QC laboratory was responsible for analysis and release of dosage forms, active ingredients, raw materials, intermediates, packing materials and environmental monitoring. The weighing of starting materials was reviewed. 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.

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 six stability chambers of which one was still under qualification, the other was standby, two (2) chambers were set at 30^0C/75%RH, one at 30^0C/65%RH and one at 40^0C/75%RH.

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 by Egyptian Drug Authority (EDA). 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.

The facility had procedure in place for validation and verification of analytical test to ensure that they meet the requirements for the intended analytical applications. 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, maintance and machine status label

6. Purified water System

The source of water was a municipal water. Water was pumped and passed through a chlorine dosing followed by a sand grade filter, carbon filter, double softners to produce soft water that was stored in HDPE storage tank. From soft water tank, water was filtered 40µ filter before treatment with Sodium Metabisulphite. After removal of chlorine by Sodium Metabisulphite water was passed through double RO system, electrical

deionizer, UV lamp and then filter. Water was then stored in the PW tank which was collected in SS316L and water was circulated at ambient condition below 18-25^{0}C to prevent microbial growth and pressurized to production area by sanitary pumps and passed through 4 UV lamps before distribution to user points.

7. Heating, Ventilation and Air Conditioning

The heating, ventilation and air conditioning (HVAC) system consists of forty-two (42) Air Handling Units (AHUs) with the aim of supplying filtered air to dedicated areas such as warehouse, production and quality control for the purpose of preventing mix-ups and cross contamination. Smoke detector was installed in the main duct to detect smoke in case of fire and stops AHU.

The AHU was consisted of blower, chilled water coil, hot water coil, dehumidifier and filters. As per schematic diagram displayed on HVAC system and physical inspection conducted, it was observed that the fresh air entered the AHUs through the primary filter of 5µm pore size followed by dehumidification and cooling then to the secondary filter of 1µm pore size to the HEPA filter where clean air was supplied to the production areas.

AHU supplied 20% fresh air to maintain differential pressure between 5 – 15 Pascal between adjacent area and number of air changes were NLT 20 air change/hour.

8. Document Review

Documentation was designed, prepared, reviewed and distributed to users according to procedure in place (SOP used by operators and technicians were in Arabic). The documents related to assurance of quality and safety of pharmaceutical products being manufactured, were prepared by the quality management department and strictly closely followed and controlled. Procedure for preparation, issuance, recording, retrieval, storage and destruction of documents and records were in place.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection Utopia Pharmaceuticals, Plot No. (2) Industrial Zone (A7)-Formerly Zizinia-Cairo-Ismailia Road-10th of Ramadan-Sharkia, Egypt is considered to be operating at an acceptable level of compliance with with TMDA Good Manufacturing Guidelines for Veterinary Medical Products, Second edition, April, 2022 for the production of General OSD for human use in form of tablets and hard gelatin Capsules, Oral Dry Powder (Sachets and Jars), oral liquid and dry powder for suspension.

This TPIR will remain valid until 19th February, 2027, provided that the facility will remain compliant following any inspections conducted in the period.

Part 4: References

1. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition
2. 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
3. TMDA (2019) Tanzania Medicines and Medical Devices Act, Cap 219
4. Utopia Pharmaceuticals Site Master File (SMF), MD-SMF-06 version 06, 2023
5. TMDA (2018) Good Manufacturing Practices Enforcement Regulations, GN 295