TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ELYS CHEMICAL INDUSTRIES LTD UNIT-II, KENYA

PUBLIC GMP INSPECTION REPORT

9th December, 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	**Elys Chemical Industries Ltd-Unit II**
Corporate address of manufacturer	No. 6, Ring 'B', Off Enterprise Road, P. O. Box 40411-00100, Nairobi, Kenya Tel: +254-20-255031/2/3/4 Fax: +254-20-6533148 Website: elys.co.ke elys@elys.co.ke
Inspected site	
Name & address of inspected manufacturing site	Elys Chemical Industries Ltd, Plot No. 209/15128, Mombasa Road P. O. Box 40411-00100, Nairobi, Kenya
Unit/ block/ workshop number	Unit II
Inspection details	
Date of inspection	2nd and 3rd May, 2019
Type of inspection	Pre-Registration Inspection
Introduction	
General information about the company and site	Elys Chemical Industries Ltd-Unit II is located at Plot No. 209/15128 about 15 kms from Nairobi City Centre and 1.5kms from Jomo Kenyatta International Airport. The facility was dedicated for the manufacture of beta-lactam products in the form of Oral Solids (tablets and capsules) and Oral powder/granules for suspension.
History	The facility had been inspected and approved by PPB, Kenya. The facility had also been inspected and approved by other NMRAs namely NDA – Uganda, Ghana, Mozambique, Zambia,

	Malawi, Uganda and Botswana.
Brief report of the activities undertaken	
Areas inspected	External surroundings, raw material receiving area, raw material and packaging materials warehouses, production areas, packing area, finished goods store, quality control laboratory and utilities.
Restrictions	Inspection focused on Beta-Lactam OSD and dry powder for suspension
Out of scope	Production lines different from restrictions above
Production lines inspected by TMDA	Production of beta-lactam products in the form of Oral Solids (tablets and capsules) and Oral powder/granules for suspension.
Abbreviations	**Meaning**
AHU	Air Handling Unit
BMR	Batch Manufacturing Records
CAPA	Corrective and Preventive Actions
EAC	East African Community
GMP	Good Manufacturing Practices
HVAC	Heating Ventilation and Air Conditioning
IPQC	In Process Quality Control
QC	Quality Control
SOP	Standard Operating Procedures

Part 2: Brief summary of the findings and comments

1. Personnel

Elys Chemical Industries Ltd –Unit II is an extension of Elys Chemical Industries Ltd - Unit I located at Road B, Off Enterprise Road in Nairobi, Kenya. Key personnel of Unit II reported directly to the administrative and technical leaders situated at Unit I. The facility had adequate staff and key posts were occupied by full time, qualified and experienced

individuals with responsibilities fully defined in their job descriptions. Heads of Production and Quality Control and their subsequent sections were independent of each other as indicated on the company organization chart.

Training programs and schedules were as per facility SOPs, as evidenced in the training records for employees availed. Medical checkups were conducted both, during initial employment and as a routine procedure.

2. Premises

The facility had two floors; the ground floor and first floor and was designed in such a way that there were separate and dedicated areas for raw materials, primary and secondary packaging and the quarantine room for finished goods.

Layout and Design

The facility was built up of concrete structure with an epoxy covered production floor. Electrical supply, lighting and temperature conditions were found appropriate for manufacturing activities. Generally, the premises were designed to ensure logical flow of materials, personnel and activities performed.

Sanitation and Hygiene

The facility had separate primary and secondary change rooms for staff (both gents and ladies) working in the manufacturing areas and all change rooms were adequate in size, clean and were provided with step over benches and hand sanitizers.

There were written procedures for gowning and de-gowning as well as pictorial presentations for entry and exit in different production areas which were placed in changing rooms. Personnel working in production areas were properly dressed with neat and clean clothes, gloves and masks.

The production rooms were clean and environmental sanitation was maintained as per SOP. SOP for cleaning validation, cleaning validation protocol and relevant records were checked and found to be properly maintained. Rodent traps were observed around the plant in order to prevent entry of rodents.

3. Production

The facility was engaged in production of different Beta-lactam products mainly oral solids (capsules and tablets) and oral powder/granules for suspension. There was a Standard Operating Procedure (SOP) for receiving of materials and list of qualified vendors at the vantage area. All incoming materials were generally controlled (quarantined, sampled, tested, released or rejected). The quarantined and approved material areas were also well marked and materials were provided with status labels as

required. Printed packaging materials were stored in secured condition in a restricted access area. There was also a storage room for intermediate products and finished goods. The finished goods were put under quarantine before release by Quality Assurance and transfer to approved finished goods warehouse at Elys Chemical Industries Unit I.

Standard Operating Procedures (SOPs) for sampling, dispensing and Environmental Monitoring were available and were checked, along with the records for temperature and humidity monitoring. The personnel handling the dispensing and sampling activities were well trained and competent to carry out their tasks.

There was one dedicated booth for both sampling and dispensing of raw materials with the provision for reverse lamina air flow cabinet and separate entry points for materials and personnel.

Review of BMR at various stages indicated that production operations followed written procedures. Checks on yields and reconciliation of quantities were carried out and the variations in the percentage yield of the product were accounted for with explanations including reconciliation of printed labels.

4. Quality Control

There was no Quality Control Laboratory in unit II. All testing except IPQC was carried out at the main QC laboratory located at Elys Chemical Industries Ltd - Unit I.

5. Equipment

The facility had sufficient number of production equipment which were designed, located, installed, qualified and maintained to suit the operations carried out.

Equipment design facilitated effective cleaning to prevent chances of contamination and cross contamination.

6. Water Treatment System

Purified water requirements were sourced from Elys Chemical Industries Ltd - Unit I. Standard Operating Procedure (SOP) and records for this process were availed for verification and found to be adequate.

7. Heating, Ventilation and Air Conditioning

The HVAC systems used 10% fresh air and 90% re-circulated air. The installation, operational and performance qualification was performed for all the AHUs. Qualification records of the respective AHUs were reviewed.

Maintenance and servicing of AHUs was done by a qualified full time employee. Monitoring records, preventive maintenance schedule and preventive maintenance records were verified.

8. Document Review

A documentation system was in place to guide production and control of products. These included updated Site Master File, Validation Master Plan (VMP); Standard Operating Procedures; qualification and validation protocols and reports.

There were corresponding records in form of reports, forms, checklists, logbooks, registers maintained as evidence of compliance with the procedures and specifications.

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 inspection report and the assessment of CAPA, **Elys Chemical Industries Ltd-Unit II, located at Mombasa Road, P.O.BOX 40411-00100, Nairobi, Kenya** was considered to be operating at **an acceptable level** of compliance with the East African GMP Guidelines for the production of beta-lactam (penicillin) medicinal products in the form of tablets, capsules and dry powder for 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. EAC-Good Manufacturing Practice Compendium, (2014), Technical Documents for Harmonization of Medicines Regulation in the East African Community
2. The Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practice Enforcement) Regulations, 2018
3. Tanzania Food, Drugs and Cosmetics Act, Cap 219.
4. Elys Chemical Industries Ltd-Unit II Inspection Report May, 2019
5. Elys Chemical Industries Ltd-Unit II Compliance Report, 2019
6. SOP for conducting inspection of pharmaceutical manufacturing facilities.