ARAB REPUBLIC OF EGYPT

EGYPTIAN DRUG AUTHORITY

C.A. OF OPERATIONS



جمهورية مصر العربية هيئــة الـدواء المصرية

الإدارة المركزية للعمليات

CERTIFICATE OF GMP COMPLIANCE

Certificate Number: P-529/2023

Part 1:

EDA confirms the following:

Name of Manufacturing Site. Egyptian International Pharmaceutical Industries Company (EIPICO).

Address of Manufacturing Site: Tenth of Ramadan City - First Industrial area B1.

Operation License Number: LiHV20220013/0011984

Purpose of the certificate: for company.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted in 2022, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice according to WHO guidelines and/or other approved international guidelines for the pharmaceutical dosage forms, categories and/or activities listed in the part 2.

Part 2:

Production Lines Human Products	
1:1	Solid dosage forms area includes (tablet-hard gelatin capsule "Powder & spansules")
1.2	Semi solid dosage forms area includes 2 production lines of (cream-ointment-gel)-3 production lines of suppositories.
1.3	Liquid dosage forms area includes (syrup-suspension-oral drops "packed in glass & plastic bottles")
1.4	Filling of purified water
1.5	β-Lactam area includes (tablet-capsule-powder for oral suspension).
2.	Sterile products
2.1	Sterile area (1) includes: Two production lines of sterile drops (eye &ear) & one production line of eye and ear drops was added on 2/4/2014.
2.2	Sterile area (2) includes production of ampoule & vials (Non hormonal) (liquid-lyophilized).
2.3	Sterile area (3) includes sterile penicillin vial "powder"
2.4	Sterile area (4) includes ampoules & vials (Non hormonal) (liquid-lyophilized).
2.5	Sterile area (5) filling lines of cephalosporin vial-new production line for cephalosporin vial was added on 2/9/2015.
2.6	Sterile area (6) includes β-Lactam vial "powder Penem"
2:7	Production line of eye ointment.
3.	Packaging
3.1	Primary packaging & Secondary packaging for all products.

• The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies was anufacturer.



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- This certificate reflects the status of the manufacturing site at the time of the inspection noted above and the period of validity may be reduced or extended using regularity risk management principle by an entry in the Restrictions or Clarifying remarks field.
- The certificate remains valid until <u>21/05/2024</u> it becomes invalid if the activities and/or categories certified here with are changed or if the site is no longer considered to be in compliance with GMP.

Dr. Amira Mangoub

General Manager of General

Administration of Factories Inspection

dr Anal Adul

22-5-2023

Authenticated, Dr. Yasin Ragaey

Head of

Central Administration of Operations

Certificate Number: P-529/2023

Issue Date: 21/05/2023

The authenticity of this certificate can be verified via scanning the QR-Code at the upper right corner

www.edaegypt.gov.eg