306240

DRUG

NATIONAL **AUTHORITY**

CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE GUIDELINES

THE NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Issued under Regulation 19(5) of the National Drug Policy and Authority (Licensing) Regulations, 2014

Certificate No. 253/GMP/2020

This is to certify that the drug manufacturing facility:

Name of facility: Egyptian International Pharmaceuticals Industries Company (EIPICO).

Physical address of facility: 10th of Ramadan city, Industrial Area BI-Egypt, P.O. Box 149 -10th - Egypt

Has been assessed by the Authority for compliance with the Good Manufacturing Practice Guidelines.

On the basis of the assessment carried out on **28th October 2020,** it is certified that the facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table 1 below.

Table 1: Approved lines

No.	*Dosage Form*	*Category*	*Activities*
1.	Tablets (Coated and Uncoated)	Non-Beta Lactam	Manufacture of Finished Pharmaceutical Product
2.	Hard Gelatin Capsules		
3.	Soft Gelatin Capsules		
4.	Creams, Ointments and Suppositories		
5.	Oral Liquids		
6.	Eye Ointments		
7.	Eye sterile Drops		
8.	Oral powder for suspension		
9.	Small Volume Parenterals-Powders-Lyophilized		
10.	Small Volume Parenterals-Solutions-Hormones		
11.	Small Volume Parenterals-Powders	Beta lactam (Cephalosporins)	
12.	Tablets (Coated &uncoated)	Beta lactam (Penicillins)	
13.	Hard Gelatin Capsules		
14.	Oral powder for suspension		

The responsibility for the quality of the individual batches of the drugs manufactured through this process lies with the manufacturer.

This certificate remains valid until **28th October 2023.** It becomes invalid if the activities or the categories certified change or if the facility is no longer considered to be in compliance with GMP.

Issue Date: 28th October 2020.

NATIONAL DRUG AUTHORITY
28 OCT 2020
PLOT 15 LUTHULI AVENUE
P. O. BOX 23052, KAMPALA

Denis Mwesigwa
FOR THE AUTHORITY

Received on 23rd/11/20

DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

2245/ID/NDA/10/2020

22nd October 2020

To: All Concerned Foreign Manufacturing Facilities

CIRCULAR NO. 009/DIE/2020

RENEWAL OF GMP CERTIFICATES

In a bid to ensure business continuity with regard to GMP activities and in an effort to avoid disruptions in the importation of medicines due to the expired validity of GMP certificates, and cognizant of the travel restrictions during this period of the COVID-19 pandemic, the National Drug Authority has resolved to extend the period of validity of your GMP certificate for 3 years.

Please note that on-site inspections to verify compliance with NDA GMP guidelines will resume as soon as there is a consensus that the period of the public health crisis has passed.

All manufacturing facilities that have received certificates under this arrangement are expected to agree to being inspected once the situation improves. The decision to maintain your GMP certification will be contingent upon the outcome of the inspection.

Please be reminded that it is your primary responsibility to ensure continued compliance of your manufacturing activities with the current good manufacturing practice requirements at all times. Any failure to meet the GMP requirements must be immediately notified to NDA.

Furthermore, you are reminded that in accordance with regulation (3) of the Pharmacovigilance Regulations, 2014, all manufacturers with GMP certificates issued by NDA should have in place an appropriate system for pharmacovigilance, preferably overseen by a registered pharmacist in Uganda to monitor the quality, safety and efficacy of your products while on the Ugandan market.

For further assistance or clarification, please don't hesitate to contact the NDA Secretariat.

Thank you for your continued cooperation.

OFFICE OF THE SECRETARY TO THE AUTHORITY

David Nahamya
SECRETARY TO THE AUTHORITY

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OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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