



የኢትዮጵያ የምግብ፣ የመድኃኒት የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለሥልጣን

FOOD, MEDICINE AND HEALTHCARE

ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA

ቁጥር 02/19/12/363  
Ref. No.

ቀን 11/1 DEC 2019  
Date:

**Egyptian International Pharmaceutical Industrial Company Site 1 (EPICO Site 1),  
10th of Ramadan city, Industrial Area B1-Egypt, P. O. Box 149-10th.**

We would like to express our thanks for the cooperation and hospitality you extended to us during the inspection of your plant which conducted on 03, 04 & 05, October 2019.

The purpose of the inspection was to determine the compliance of the manufacturing plant with the principles of current Good Manufacturing Practice (cGMP) as a complement to market authorization of pharmaceutical products in Ethiopia. The level of compliance of the company's facilities and operations with the principles of current Good Manufacturing Practices ( cGMP) for the manufacture of non hazardous general non-sterile oral products(tablet, capsules & oral liquids) products is **acceptable. But** the level of compliance of the company's facilities and operations with the principles of current Good Manufacturing Practices ( cGMP) for the manufacture of *sterile beta lactam cephalosporin, sterile beta lactam penicillin and none sterile beta lactam penicillin, general sterile* products **is not acceptable.**

Accordingly, the authority would like to inform you that your plant is **acceptable** to register and distribute its products (general non-sterile oral products (tablet, capsules & oral liquids)) from the above mentioned manufacturing site (EPICO Site1).

In the meantime deficiencies which were observed during the inspection time as indicated in the attachment (7 Pages) needs to be corrected and reported through CAPA plan

C.C:

- ✦ ATMA IMPORT AND EXPORT  
Addis Ababa
- ✦ Director General
- ✦ Medicine Facility Inspection Directorate
- ✦ Medicine Registration and Licensing Directorate
- ✦ Central Ethiopia Branch Office  
EFMHACA



With Best Regards,

*GA*  
**Getachew Genete**  
Facility Inspection  
Directorate Director

P.O.Box: 5681 ፋክስ/Fax: 251 552 13 92

Tel. 251 552 41 22/52 41 23

www.fmhaca.gov.et E-mail: [regulatory@fmhaca.gov.et](mailto:regulatory@fmhaca.gov.et) መልስ በሚሰጡበት ጊዜ የእኛን ደብዳቤ ቁጥር ይጥቀሱ

IN REPLY REFER TO OUR Ref. No.