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FOOD MEDECINE AND HEALTH CARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA (FMHACA)

ቁጥር 02/9/12/25
Ref.No.

ቀን 27 AUG 2021
Date

TO: World Medicine Pharmaceutical Industry and Trade Incorporated

15 temmuzmah, camiyolu cad.no:50 GunesliBagcilar/Istanbul, 34212, Turkey

The Authority would like to express its gratitude for the cooperation and hospitality you extended during the inspection of your plant from May 25-27/2021. The purpose of the inspection was to determine the compliance of the manufacturing plant with the principles of Good Manufacturing Practice (GMP) as a complement to market authorization.

The level of compliance of the company's facilities and operations for pharmaceutical products with the principles of cGMP for medicinal products was found to be **acceptable for the General production lines of tablets, capsule (powder/granule) filling, sachet filling, oral solution, suppository, soft gelatine capsule, sterile eye drop and Not acceptable for production of Pellet filling lines.**

Accordingly, the authority would like to inform you that your plant is **accepted** to register and distribute its products from the above-accepted manufacturing lines. Hence, you are required to correct the deficiencies which were observed during the inspection time and report through CAPA plan as indicated in the attachment (**1 Pages**).

With Best Regards

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Medicine Facility Inspection Directorate Director

C.C:

- Biliham Pharmaceuticals
  Addis Ababa
- Medicine Registration and Licensing Directorate
- Medicine Facility Inspection Directorate
- Central Ethiopia Branch Office
  EFDA

ፋክስ/Fax: 251-11-552 1392 P.O.Box: 5681 Tel . 251-11-552 4122/552 4123 Website: www.fmhaca.gov.et E-mail: regulatory@fmhaca.gov.et
IN REPLY REFER TO OUR REF. NO.
መልስበሚሰጠበትጊዜየእኛንደብዳቤቁጥርይጥቀሱ