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

Ref.No. 02/9/12/125

Date 27 AUG 2021

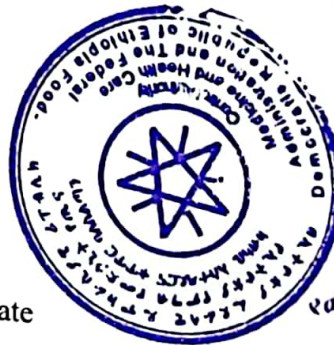
TO: World Medicine Pharmaceutical Industry and Trade Incorporated

15 temmuzmah, camivolu 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

C.C:

Biliham Pharmaceuticals

Addis Ababa

Medicine Registration and Licensing Directorate

Medicine Facility Inspection Directorate

Central Ethiopia Branch Office

EFDA

Getachew Genete
Medicine Facility Inspection
Directorate Director

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IN REPLY REFER TO OUR REF. NO.
ማለት ማስታወሻ ለዚህ ደብዳቤ ቁጥር ይጥቀሱ

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