



ETHIOPIAN ACCREDITATION SERVICE

ACCREDITATION CERTIFICATE

Issue No. 01

**Ethiopian Food and Drug Authority
Medicine Facility inspection Directorate
(EFDA-MFID)**

Addis Ababa, Ethiopia

Facility Accreditation No: **IB0013**

Is accredited by the Ethiopian Accreditation Service (**EAS**) to perform sampling and inspection in accordance with the attached scope of accreditation in the field of:-

- **Medicine & Medicinal Facility Inspection**

The **IB**; EFDA-MFID is accredited in accordance with the requirements of **ISO/IEC 17020:2012: Conformity assessment-General requirements for the operation of various types of bodies performing inspection**, This accreditation status declares competence of the IB for demonstration of the technical and quality management system on defined scopes of operation. While this certificate remains valid; the accredited facility named above is authorized to use the relevant **EAS & ILAC-MRA** accreditation symbols to issue inspection reports and/or certificates.

Effective Date: 21 Feb 2022

Certificate Expires: 21 Aug 2026

Mrs. Meseret Tessema
Director General
Ethiopian Accreditation Service



SCOPE OF ACCREDITATION

Type of Inspection Body: **Type "A"**
Facility Accreditation No: **IB0013**

<p>Permanent Address:</p> <ul style="list-style-type: none"> Ethiopian Food and Drug Authority; Medicine Facility inspection Directorate (EFDA-MFID) <p>Postal Address:</p> <ul style="list-style-type: none"> 5681, Addis Ababa, Ethiopia <p>Tel: +251-115524422 +251-115523306</p> <p>Fax: +251-115521392</p> <p>Email: contactefda@efda.gov.et</p>		<p>Management Signatory:</p> <p>Mr. Getachew Genete</p> <p>Technical Signatories:</p> <ul style="list-style-type: none"> :Mr Getachew Genete :Mr. Samuel Marie :Mr Mengistu Endalew :Mr Wondu Ketele :Mss Kalkidan Yihenew :Mss Haimanot Ayele :Mr Debebe Argaw :Mrs Mahlet Million :Mss Feruza Muhammed <p>Nominated Representative:</p> <ul style="list-style-type: none"> Mr Samuel Marie & Mr Mengistu Endalew <p>Original date of Accreditation: 21Feb2022</p> <p>Issue No: 01</p> <p>Issue Date: 21 Feb2022</p> <p>Expiry date: 21 Aug 2026</p>	
Field of Inspection	Item	Type and range of inspection	Inspection Scheme or Regulation Code
Medicine and Medicine Facility Inspection	<ul style="list-style-type: none"> Large Scale Medicine Manufacturing Facility 	<ul style="list-style-type: none"> Physical Inspection; As per Small Scale Medicine Facilities Establishment Directive & Good Manufacturing Practice 	<ul style="list-style-type: none"> L.M.M.F Directive (No. 830/2021) L.M.M.F Guideline(2014 edition) SOP for cGMP (SOP/MFID-GEN 005)
	<ul style="list-style-type: none"> Small Scale Medicine Manufacturing Facility 	<ul style="list-style-type: none"> Physical Inspection; As per Small Scale Medicine Facilities Establishment Directive 	<ul style="list-style-type: none"> S.M.M.F Directive(No.339/2020) (SOP/MFID-PROC020)
	<ul style="list-style-type: none"> Medicine Import, Export & Wholesale 	<ul style="list-style-type: none"> Physical Inspection & Sampling; As per the Medicines Control Directive & Guideline 	<ul style="list-style-type: none"> M.I.E.W Directive (No.10/2005) M.I.E.W Guideline (2015 edition) SOP of GxP (SOP/MFID-GEN009) Sampling;(SOP/MFID-PROC018)

Meseret Tessema Seyfu
Director General



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Field of Inspection	Item	Type and range of inspection	Inspection Scheme or Regulation Code
Medicine & Medicine Facility Inspection	Medicine Products	<ul style="list-style-type: none">• Post-Marketing Quality Surveillance (PMS); As per Guideline for Post-Marketing Quality Surveillance of Medicines	<ul style="list-style-type: none">• Risk-based PMS Guideline (June2020)• SOP for Risk-based PMS (SOP/MFID-PROC-002)• SOP for Sampling (SOP/MFID-PROC018)• SOP of PMS Sentinel Site selection, (SOP/MFID-PROC-019)

Meseret Tessema Seyfu
Director General