



ETHIOPIAN NATIONAL ACCREDITATION SERVICE

ACCREDITATION CERTIFICATE

Issue No. 02

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

Addis Ababa, Ethiopia

Facility Accreditation No: **IB0019**

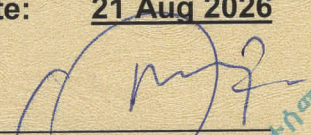
Is accredited by the Ethiopian National Accreditation Office (**EAS**) to perform Sampling and Inspection in accordance with the attached Scope of Accreditation in the field of:-

▪ **Medicine & Medicinal Facility Inspection**

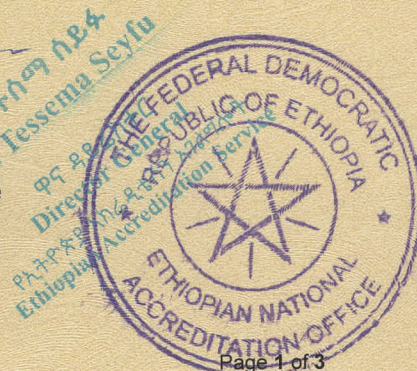
The **IB** is accredited in accordance with the requirements of **ISO/IEC 17020:2012; Conformity assessment-General requirements for the operation of various types of bodies performing inspection**, This accreditation demonstrates technical competence for the defined scope and the operation of an inspection body's quality management system. 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: 05 Oct 2022

Expiry date: 21 Aug 2026


Mrs. Meseret Tessema
Director General
Ethiopian Accreditation Service

Issued by: Ethiopian Accreditation Service





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SCOPE OF ACCREDITATION

Type of Inspection Body: Type "A"

Facility Accreditation No: IB0019

Permanent Address:

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

Postal Address:

5681, Addis Ababa, Ethiopia

Tel: +251-115524422

+251-115523306

Fax: +251-115521392

Email: contactefda@efda.gov.et

Management Signatories: Mr. Getachew Genete

Technical Signatories: Mr. Getachew Genete

:Mr. Samuel Marie

:Mr Mengistu Endalew

:Mr Wondu Ketele

:Ms Kalkidan Yihenew

:Ms Hayimanot Ayele

:Mr Debebe Argaw

:Mrs Mahlet Million

:Ms Feruza Muhammed

Nominated Representative: Mr Samuel Marie & Mr Mengistu E.

Original date of Accreditation: 21Feb2022

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Field of Inspection	Item	Type and range of inspection	Inspection Scheme or Regulation Code
Medicine and Medicine Facility Inspection	Large Scale Medicine Manufacturing Facility	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)
	Small Scale Medicine Manufacturing Facility	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)
	Medicine Import, Export & Wholesaler	Sampling & Inspection; 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-GEN-009) • Sampling; (SOP/MFID-PROC018)

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Field of Inspection	Item	Type and range of inspection	Inspection Scheme or Regulation Code
Medicine & Medicine Facility Inspection	Medicine Products	Sampling & 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)



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