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ETHIOPIAN NATIONAL ACCREDITATION OFFICE

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ACCREDITATION CERTIFICATE

Ethiopian Food and Drug Authority
Medicine Facility Inspection Directorate
(EFDA-MFID)
Addis Ababa,
Ethiopia.

Facility Accreditation No: IB0013
Issue No. 01


Is accredited by the Ethiopian National Accreditation Office (ENAO) to perform Sampling and Inspection in accordance with the attached Scope of Accreditation in the field of;

- Medicine & Medicine 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*. The 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 ENAO & ILAC-MRA accreditation symbols to issue inspection reports and/or certificates.

Effective Date: 21 Feb 2022

Expiry date: 21 Aug 2026


Ato Araya Fesseha
Director General
Ethiopian National Accreditation Office





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ETHIOPIAN NATIONAL ACCREDITATION OFFICE

SCOPE OF ACCREDITATION

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

<p>Permanent Address: Ethiopian Food and Drug Authority; Medicine Facility inspection Directorate EFDA-MFID</p> <p>Postal Address: 5681 Addis Ababa, Ethiopia</p> <p>Tel: +251-115524422 (+251-115523306) Fax: +251-115521392 Email: contactefda@efda.gov.et</p>		<p>Management Signatories: Mr. Getachew Genete</p> <p>Technical Signatories: Mr. Getachew Genete :Mr. Samuel Marie :Mr. Mengistu Endalew :Mr. Wondu Ketele :Mr. Mohamed Ali :Mr. Debebe Argaw</p> <p>Nominated Representative: Mr. Mengistu Endalew : Mr. Samuel Marie</p> <p>Original date of Accreditation: 21 Feb 2022 Issue No: 01 Effective Date: 21 Feb 2022 Expiry date: 21 Aug 2026</p>	
Field of Inspection	Item	Type and range of inspection	Inspection Scheme or Regulation Code
Medicine & Medicine Facility Inspection	Large Scale Medicine Manufacturing Facility	Inspection; As per the Medicine Good Manufacturing Practice- GMP; Directive, Guideline, & SOP	<ul style="list-style-type: none"> ▪ Directive No. 830/2021 ▪ Guideline 2014 (1st edition) ▪ SOP of cGMP; (SOP/MFID-GEN 005)
	Small Scale Medicine Manufacturing Facility	Inspection; As per the Small Scale Medicine manufacturing Establishment; Directive, & SOP	<ul style="list-style-type: none"> ▪ Directive No. 339/2020 ▪ (SOP/MFID-PROC020)
	Medicines; Import, Export, and Wholesale	Inspection; As per the Medicines Control; Directive, Guideline, & SOPs	<ul style="list-style-type: none"> ▪ Directive No. 10/2005 ▪ Guidelines Sept. 2015 (1st edition) ▪ SOP of GxP; (SOP/MFID-GEN-009) ▪ SOP of Sampling; (SOP/MFID-PROC018)



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 Aya Fesseha Gezehegn
 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	Sampling & Post-Marketing Quality Surveillance (PMS) As per Guideline, & SOPs for Post-Marketing Quality Surveillance of Medicines in Ethiopia,	<ul style="list-style-type: none"> ▪ Risk-based PMS; Guideline June 2020 ▪ SOP of Risk-based PMS; (SOP/MFID-PROC-002) ▪ SOP of Sampling; (SOP/MFID-PROC018) ▪ SOP of PMS Sentinel Site selection; (SOP/MFID-PROC-019)

