



RWANDA FDA
Rwanda Food and Drugs Authority

Doc N°: DD/PIL/FMT/001

Version: 6

Effective Date: 18/05/2026

Certificate N°: **RWANDA-FDA26/GMP/O/MED/0006-0037-2734**

CERTIFICATE OF COMPLIANCE
with
Good Manufacturing Practices

Pursuant to Law N°. 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning, especially in its article 9 (2);

Rwanda FDA hereby issues this certificate of compliance with current Good Manufacturing Practices requirements to the manufacturing site with details described below:

Name of manufacturing site: Agio Pharmaceuticals Ltd

Manufacturing license number: PD -100, PD-163

Site address: T- 81, 82. M.I.D.C., Bhosari, Pune 411026 Maharashtra State

Country: India

Phone number: +91-20-40730000

Email: agio@agio-pharma.com

On the basis of the **recognition assessment carried out on 11/05/2026**, Rwanda FDA certifies that the manufacturing site indicated on this certificate complies with Good Manufacturing Practices guidelines for product category(ies), dosage form(s), and activities listed in the table below:

N°	Product category(ies)	Dosage form(s)	Activity(ies)
1.	General products	Non-sterile: Oral Solids, Oral Liquids, Dry Powders and External Preparations Sterile: Small Volume Parenteral Liquids	Processing operations, batch certification, packaging, quality control testing

Validity: **Three (3) years** from the last date of assessment.

Prof. Emile BIENVENU
Director General



Page 1 of 2

Important notice

1. The responsibility for the quality of the individual batches of products manufactured through this process lies with the manufacturer;
2. This certificate becomes invalid if the activity(ies) or the category(ies) certified change or if the facility is no longer rated to comply with Good Manufacturing Practice;
3. This certificate is valid for three (3) years from the **last date of assessment** unless otherwise revoked or suspended by the Rwanda FDA;
4. The application for GMP certificate renewal shall be done six months before its date of expiry.