



REPUBLIC OF KENYA
MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Telephone: +254 0709 770 100
Email: info@ppb.go.ke
Website: web.pharmacyboardkenya.org

Pharmacy and Poisons Board Building
Lenana Road
P.O Box 27663-00506
Nairobi, Kenya

GMP CERTIFICATE No: PPB/INS/GMP/FPP/CERT/019/25

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

PART 1

Issued in accordance with the Pharmacy and Poisons Act (Cap 244) of the Laws of Kenya.

The manufacturer: **Agio Pharmaceuticals Ltd.**

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

Has been inspected in connection with Marketing Authorization(s) listing manufacturers located outside Kenya.

From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on **25th – 26th November 2024**, GMP Report No. **PPB/INS/GMP/RPT/010/25**, the site complies with the prescribed Good Manufacturing Practices as per the relevant WHO Technical Report Series and other internationally acceptable guidelines.

This certificate reflects the compliance status of the manufacturing site as at the time of the inspection above and will be deemed to be valid until **25th November 2027** after which time the Pharmacy and Poisons Board should be consulted.

PART 2

Human Medicinal Products

1. Manufacturing operations authorised/subject to inspection

1.1	Sterile Products		
	1.1.1 Aseptically prepared		
	CATEGORY	PRODUCT TYPE	ACTIVITIES
	General	Small Volume Parenteral Liquids	Processing operations, batch certification, packaging, quality control testing
	1.1.2 Testing or batch release only: N/A		
1.2	Non-sterile products		
	DOSAGE FORM	CATEGORY	PRODUCT TYPE
	Oral Solids	General	Tablets, Capsules, Dry Syrups
	Oral liquids	General	Syrups, Suspensions, Solutions
	External Preparations	General	Creams, Ointments, Gels,
	1.2.1 Testing and batch release only: N/A		
1.3	Biological medicinal products: N/A		
1.4	Other products or manufacturing activity: N/A		
1.5	Packaging only		
	1.1.1 Primary packing: N/A		
	1.1.2 Secondary packing: N/A		
1.6	Quality Control testing: N/A		
1.7	Blinding: N/A		

The compliance status shall be deemed valid unless it is invalidated under any of the following conditions;

1. The activities and/or categories certified herewith are changed.
2. The site is no longer considered to be in compliance with GMP.
3. The manufacturing site is changed.

Any restrictions or clarifying remarks related to the scope of this certificate. YES/NO

This certificate is valid only when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified with the Kenya Pharmacy and Poisons Board.

REGISTRAR/CEO
PHARMACY AND POISONS BOARD
 Tel: 0709 770100 R
 P. O. Box 27663 - 00506,
NAIROBI.
Date: 6th February 2025

F. M. Siyoi

DR. F. M. SIYOI
REGISTRAR/CHIEF EXECUTIVE OFFICER
PHARMACY AND POISONS BOARD