306068

DRUG

NATIONAL **AUTHORITY**

CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE GUIDELINES

THE NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Issued under Regulation 19(5) of the National Drug Policy and Authority (Licensing) Regulations, 2014

Certificate No. 316/GMP/2020

This is to certify that the drug manufacturing facility:

Name of facility: Agio Pharmaceuticals Limited.

Physical address of facility: T- 81, 82, MIDC, Bhosari, Pune - 411 026, Maharashtra State, India.

Has been assessed by the Authority for compliance with the Good Manufacturing Practice Guidelines.

On the basis of the assessment carried out on **14th December 2020,** it is certified that the facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table 1 below.

Table 1: Approved lines

No.	Dosage form	Category	Activities
1.	SVP solutions	Non-Beta Lactam	Manufacture of Finished Pharmaceutical (medicinal) Product
2.	Cream/ ointment/ Gel		
3.	Tablets		
4.	Oral liquid formulations		
5.	Hard Gelatin Capsule		
6.	Oral dry powders packed in sachets		

The responsibility for the quality of the individual batches of the drugs manufactured through this process lies with the manufacturer.

This certificate remains valid until **14th December 2023.** It becomes invalid if the activities or the categories certified change or if the facility is no longer considered to be in compliance with GMP.

Issue Date: 14th December 2020.

NATIONAL DRUG AUTHORITY
14 DEC 2020
PLOT 19 LUMUMBA AVENUE
P. O. BOX 28755 KAMPALA

Denis Mwesigwa
FOR THE AUTHORITY