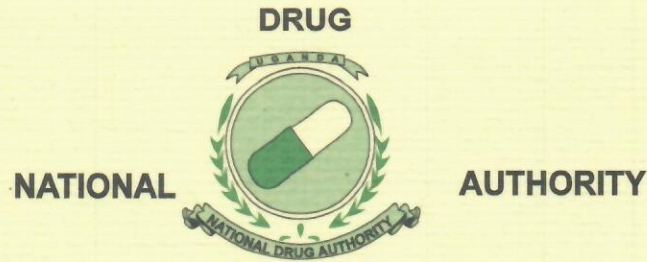


306068



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.

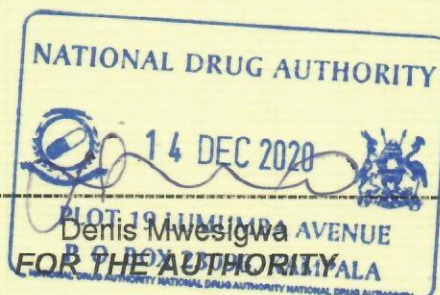
Table 1: Approved lines

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



AUTHORITY

2245/ID/NDA/10/2020

22nd October 2020

To: All Concerned Foreign Manufacturing Facilities

CIRCULAR NO. 009/DIE/2020

RENEWAL OF GMP CERTIFICATES

In a bid to ensure business continuity with regard to GMP activities and in an effort to avoid disruptions in the importation of medicines due to the expired validity of GMP certificates, and cognizant of the travel restrictions during this period of the COVID-19 pandemic, the National Drug Authority has resolved to extend the period of validity of your GMP certificate for 3 years.

Please note that on-site inspections to verify compliance with NDA GMP guidelines will resume as soon as there is a consensus that the period of the public health crisis has passed.

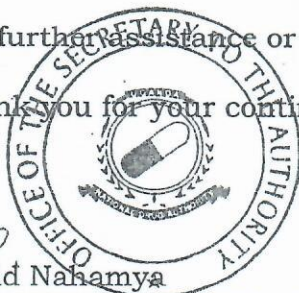
All manufacturing facilities that have received certificates under this arrangement are expected to agree to being inspected once the situation improves. The decision to maintain your GMP certification will be contingent upon the outcome of the inspection.

Please be reminded that it is your primary responsibility to ensure continued compliance of your manufacturing activities with the current good manufacturing practice requirements at all times. Any failure to meet the GMP requirements must be immediately notified to NDA.

Furthermore, you are reminded that in accordance with regulation (3) of the Pharmacovigilance Regulations, 2014, all manufacturers with GMP certificates issued by NDA should have in place an appropriate system for pharmacovigilance, preferably overseen by a registered pharmacist in Uganda to monitor the quality, safety and efficacy of your products while on the Ugandan market.

For further assistance or clarification, please don't hesitate to contact the NDA Secretariat.

Thank you for your continued cooperation.



David Nahamya

SECRETARY TO THE AUTHORITY

HEAD OFFICE

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OUR MISSION

Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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