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

DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

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.

OFFICE OF THE SECRETARY TO THE AUTHORITY

David Nahamya
SECRETARY TO THE AUTHORITY

HEAD OFFICE
Plot 19 Lumumba Avenue P.O. Box 23096, Kampala, Uganda
Tel: (+256) 417 788 100/1 (+256) 417 788 124/417 788 129
Toll Free: 0800 101 999, 0791 415 555
Website: www.nda.or.ug, Email: ndaug@nda.or ug
Facebook: Uganda National Drug Authority
Twitter: @UNDAuthority
NATIONAL DRUG QUALITY CONTROL LABORATORY
Tel: (+256) 414 540 067 / (+256) 414 583 095

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

REGIONAL OFFICES
Central Region, Nakawa- Tel: +256 393 261 548,
Western Nile Region, Arua - Tel: +256 414 671 033,
South Western Region, Mbarara- Tel: +256 414 671 034,
South Eastern Region, Jinja - Tel/ Fax: +256 434 122 176,
Eastern Region, Tororo - Tel: +256 454 445 195,
Western Region, Hoima- Tel:/Fax +256 465 440 688,
Northen Region, Lira- Tel/Fax +256 414 671 032