



Ministry of Health
of the Republic of Uzbekistan



Agency on Development of
Pharmaceutical Industry



Center of good practices

GMP – GOOD MANUFACTURING PRACTICE

CERTIFICATE

No. GMP_UZ – 08:2024

Is issued on the basis of a completed pharmaceutical inspection conducted in accordance with the regulation on the procedure for conducting inspections for compliance with the requirements of good manufacturing practice (GMP).

**STATE UNITARY ENTERPRISE
"CENTER OF GOOD PRACTICES" APPROVES**

located at

Plot No.T-81, 82, M.I.D.C, Bhosari, Pune, Maharashtra State, India-411026

"AGIO PHARMACEUTICALS LTD"

*Compliance with the requirements of
O‘zDSt 2766:2018 – “Good Manufacturing Practice - GMP”*

The basis for pharmaceutical inspection was appeal of "AGIO PHARMACEUTICALS LTD" dated 7th July, 2023 in accordance with the requirements of O‘zDSt 2766:2018 - "Good Manufacturing Practice-GMP".



GOOD MANUFACTURING PRACTICE — GMP CERTIFICATE APPENDIX

I. Sterile Products

1. Aseptically prepared (list of dosage forms):

- large volume liquids
 - small volume liquids**
 - dispersions
 - lyophilisates
 - solids
 - semi-solids
 - other aseptically prepared products:
-

(the type of medicine or the type of activity is shown).

2. Medicines subject to sterilization at the end of production:

- large volume liquids
 - small volume liquids**
 - solids and implants
 - semi-solids
 - other terminally sterilised prepared products:
-

(the type of medicine or the type of activity is shown).

GOOD MANUFACTURING PRACTICE — GMP CERTIFICATE APPENDIX

II. Non-sterile products

capsules, hard shell

capsules, soft shell

chewing gums

impregnated matrices

liquids for external use

liquids for internal use

medicinal gases

other solid dosage forms

pressurised preparations

radionuclide generators

semi-solids

suppositories

tablets

transdermal patches

intraruminal devices

other non-sterile medicinal product:

powder for oral solution

(the type of medicine or the type of activity is shown).

III. Biological medicinal products

blood products

immunobiological products

cell therapy products

gene therapy products

tissue engineered products

biotechnology products

animal extracted products

other biological medicinal products:

(the type of medicine or the type of activity is shown).

GOOD MANUFACTURING PRACTICE — GMP CERTIFICATE APPENDIX

IV. Other products or manufacturing activity

- herbal products
- homoeopathic products
- other product

(the type of medicine or the type of activity is shown).

Based on the information obtained during the pharmaceutical inspection conducted on 05-08.09.2023 and 27.02.2024 the applicant complies with the requirements of the Good Manufacturing Practice - GMP. The certificate is valid if all its pages (both main pages and additional pages) are presented. The validity of this certificate can be checked from the database of the State unitary enterprise "Center of Good Practices". If the certificate is not provided in the indicated database, it is necessary to contact the working body that issued it.

The GMP_UZ – 08:2024 Good Manufacturing Practice - GMP certificate
validity period from **12.03.2024** to **11.03.2027**

**Director
of the SUE "Center of Good Practices"**



S.P.

(signature)

Dusmatov A.F.
(full name)