Analytical Expertise Center

CERTIFICATE № IND1/12/2023

of Good Manufacturing Practice (GMP) compliance of a manufacturer

Manufacturing site name / address / contacts	**"Agio Pharmaceuticals Limited"** T-81, 82, M.I.D.C, Bhosari, Pune – 411026 Maharashtra India. Phone: +91-22-2851-8206/07
Activities carried out by company	Manufacturing, quality control, packaging, storage, batch release, distribution and marketing of: general coated and uncoated tablet, hard gelatin capsule (with powder and pellet), liquid dosage form (syrup and suspension), powder (oral powder) and external preparation (ointment, gel and cream)
Inspection date(s)	11-15.12.2023
Inspection criteria	European Union (EU) Guidelines for Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use and other related guidelines, technical reports
Scope of certification	General coated and uncoated tablet, hard gelatin capsule (with powder and pellet), liquid dosage form (syrup and suspension), powder (oral powder) and external preparation (ointment, gel and cream)
Conclusion	From the knowledge gained during inspection of the manufacturer, which was conducted between 11 and 15 December 2023 and following the evaluation of the CAPA report submitted on October 11, 2024, it is considered that the manufacturer complies with the EU GMP and Azerbaijan GMP requirements.
Notes	·This certificate reflects the status of the manufacturing site at the time of the inspection ·In case of significant changes of the inspected areas the manufacturer should inform the Analytical Expertise Center ·This certificate is valid during the three years from the last date of the inspection · Azerbaijani version of this certificate is in the internal register of Analytical Expertise Center

Date of issue: 15.12.2023

Date of expiry: 15.12.2026

AZƏRBAYCAN RESPUBLİKASI SƏHİYYƏ NAZİRLİYİ "ANALİTİK EKSPERTİZA MƏRKƏZİ" PUBLİK HÜQUQİ ŞƏXSİ
AZERBAIJAN REPUBLIC MINISTRY OF HEALTH "ANALYTICAL EXPERTISE CENTER" PUBLIC LEGAL ENTITY

General Director

Murad Suleymanov