Audit report
GM Pharmaceuticals Ltd., Tbilisi, Georgia

Audit dates: 08-09 February 2022

Audited site: GM Pharmaceuticals Ltd., 65 Qvemo Phonichala, 0165 Tbilisi, Georgia

Website: gmp.ge

Activities carried out by the company: Manufacture of finished non-sterile products (tablets, capsules, dragees, powders, granules, caplets, liquids for internal use). Storage of bulk products for primary and/or secondary packaging, storage of packaging materials for primary and secondary packaging. Primary and secondary packaging of non-sterile dosage forms. Secondary packaging of sterile dosage forms. Activities include quality control, product release and storage of finished products.

Only manufacturing of non-sterile solid dosage form products was in scope for the audit.

Audit team:
Lead Auditor: Tina Brouer, Pharmakon, Danish College of Pharmacy Practice, Collaborating Partner to WHO, Hilleroed, Denmark.
Auditor: Anders Clausen, c-Compliance, Bagsvaerd, Denmark.

References: EudraLex, Volume 4, Part I, the rules governing medicinal products in the European Union, Guide to good Manufacturing practices, Medicinal products for human and veterinary use including relevant Annexes.

Conclusion:
The overall conclusion is that GM Pharmaceutical complies with EU GMP. Processes, procedures and records were generally found in order. The storage facilities, production and laboratory premises are suitable for their intended use, clean and well organised.

Tina Brouer Anders Clausen

Lead auditor: Tina Brouer / **Auditor**: Anders Clausen
Date: 01 March 2022