



REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND
MEDICAL DEVICES AGENCY

TURKISH MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

Certificate No: TR/GMP/2022/26

CERTIFICATE OF GMP COMPLIANCE OF MANUFACTURER

Part 1

Issued following an inspection in accordance with current Good Manufacturing Practice Guidelines, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use* and the Law No 1262 on Pharmaceutical and Medicinal Preparations. These regulations are in line with the requirements of Pharmaceutical Inspection Co-operation Scheme (PIC/s) and the Directives of the European Commission.

Turkish Medicines and Medical Devices Agency confirms the following:

Manufacturer's Name : Carolina Pharma İlaç Ve Kimyevi Maddeler San. ve Tic. Ltd. Şti.
Head Office / Correspondence Address: Karaduvar Mahallesi Serbest Bölge 11. Cadde No:24 Akdeniz / Mersin / TÜRKİYE
Site Address : Karaduvar Mahallesi Serbest Bölge 11. Cadde No:24 Akdeniz / Mersin / TÜRKİYE
Manufacturing Authorization Date : 28/12/2021
Manufacturing Authorization Number : TR/ÜY/2021/13-0

Has been inspected in accordance with current Good Manufacturing Practice Guidelines, the Regulation on Manufacturing Plants of Medicinal Products for Human Use, the Law No 1262 on Pharmaceutical and Medicinal Products.

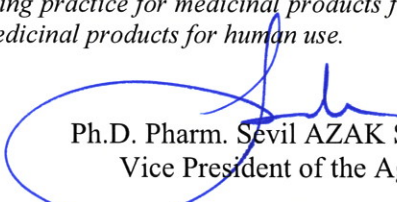
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 25-27/10/2021, it is considered that it complies with the requirements of Good Manufacturing Practice (GMP).

This certificate reflects the status of the manufacturing site at the time of the inspection, and Turkish Medicines and Medical Devices Agency should be consulted to verify compliance of the manufacturing site with GMP requirements if more than 3 years have elapsed since the date of inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified by Turkish Medicines and Medical Devices Agency upon request.

**This regulation is aligned with European Union Directive Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use, and Directive 2001/83/EC on the Community code relating to medicinal products for human use.*


Ph.D. Pharm. Sevil AZAK SUNGUR
Vice President of the Agency

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
Tel: (0312) 218 30 00 Fax: (0312) 218 34 60

Part 2

■ Human Medicinal Products

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS	
<i>If the company is engaged in manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphanomides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.</i>	
1.2	Non-sterile products
1.2.1	Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell - Capsule, hard 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use - Syrup 1.2.1.11 Semi-solids - Gel - Ointment 1.2.1.13 Tablets - Coated tablet - Tablet
1.2.2	Batch certification
1.5	Packaging
1.5.1	Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 1.5.1.13 Tablets
1.5.2	Secondary packaging
1.6	Quality control testing
1.6.2	Microbiological (non-sterility)
1.6.3	Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate :

1.2.1.1 Capsule, hard: It is valid for hard gelatin capsule.

1.2.1.5 Liquids for external use: It is valid for suspension.

1.2.1.6 Liquids for internal use: It is also valid for suspension.

18/01/2022 TR/GMP/2022/26

Ph.D. Pharm. Sevil AZAK SUNGUR
Vice President of the Agency

