Republic of Turkey
Ministry of Health
Medicines and Medical Devices Agency of Turkey

TURKISH MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

Certificate No: TR/GMP/2018/188

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	: Deva Holding A.Ş.
Head Office / Correspondence Address	: Halkalı Merkez Mahallesi, Basın Ekspres Caddesi, No: 1, Küçükçekmece / İstanbul / TÜRKİYE
Site Address	: Dumlupınar Mahallesi, Ankara Caddesi No:2, Kartepe/Kocaeli/TÜRKİYE
Manufacturing Authorization Date	: 19/11/2008
Manufacturing Authorization Number	: 2008/8

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 06-09/03/2018, 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.*

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

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Part 2

☐ Human Medicinal Products

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS	
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.	
1.1	**Sterile Products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids (Injectable solution, Infusion solution, Solvent for parenteral application) 1.1.1.2 Lyophilisates (Injectable solution lyophilisation, Infusion solution lyophilisation, Injectable suspension lyophilisation) 1.1.1.4 Small volume liquids (Injectable solution, Infusion solution, Solvent for parenteral application, Injection suspension, Injectable emulsion, Infusion emulsion, Eye drop, Ear / Eye Drop-solution, Eye drop emulsion, Eye drop suspension, Eye drop preparation solvent, Extended eye drop, Eye Lotion)
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids (Injectable solution, Infusion solution, Solvent for parenteral application) 1.1.2.3 Small volume liquids (Injectable solution, Infusion solution, Solvent for parenteral application)
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilization of active substances/excipients/finished products 1.4.2.1 Filtration 1.4.2.3 Moist heat
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological (sterility)
	1.6.2 Microbiological (non-sterility)
	1.6.3 Chemical/Physical

03/09/2018

TR/GMP/2018/188

Fatih TAN
Vice President of Inspectorate

Ministry of Health Republic of Turkey
Turkish Medicines and Medical Devices Agency

REPUBLICA MOLDOVA, mun. CHIŞINĂU
SOCIETATEA DE ACTIUNI "SANFARM-PRIM" S.A.
Nr. 1002600039072

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
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MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000

Good Manufacturing Practice Certificate

TT60-1003-41-3-2

To whom it may concern

This is to certify that **Deva Holding A.Ş.** operating at **Dumlupinar Mah. Ankara Caddesi No 2, Kartepe, Kocaeli, Turkey 41250** has been audited to the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 1: Manufacture of Pharmaceutical Products, and has been found to comply with the requirements for:

Manufacture, testing and release for supply of:

- **Iloprost (Vebulis) – solution for nebulisation and inhalation**
- **Spazmol – solution for injection**
- **Tenoxicam – powder for injection**

The following person is currently nominated as the person responsible for release for supply:

Gülçe GÖKBULUT ÖZASLAN, Quality Operations Manager

This certification is based on an audit carried out by officers of the Ministry of Health at the Company's site on 20, 21, 22 and 23 May 2019.

This certificate is valid until 9 August 2022.

MINISTRY OF HEALTH
133 MOLESWORTH STREET
WELLINGTON
NEW ZEALAND

Derek Fitzgerald
Manager, Compliance Management Branch, Medsafe
9 February 2021