



Certificate No: 201/2026/GMP

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1,2}

Part 1

Issued following an inspection in accordance with Art. 94 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products

The competent authority of Republic of Bulgaria confirms the following:

The manufacturer: **"BALKANPHARMA-RAZGRAD"AD**

Site address: 68, Aprilsko Vastanie Str, 7200 Razgrad, Bulgaria

Has been inspected under the national inspection programme of Bulgarian Food Safety Agency in relation with manufacturing authorization no 03/24.03.2023 issued to **"BALKANPHARMA-RAZGRAD"AD**, situated at the address: 68, Aprilsko Vastanie Str., 7200 Razgrad, Bulgaria in accordance with Art. 88 of Regulation (EU) 2019/6 and the following national legislation: Art. 316, para 1 of the Law on veterinary activity, enforced on 1ST May, 2006 and promulgated in the SG 87 on 1st November, 2005

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **23. 01.2026**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC³.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that 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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu>).

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

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Done in Sofia on 23th of March, 2026

3/25/2026

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DR. KRASIMIR KOLEV
DEPUTY EXECUTIVE DIRECTOR
Signed by: KRASIMIR KOLEV KOLEV

1 The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 94(1) of Regulation (EU) 2019/6 is also applicable to importers.

2 Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

Part 2 Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	Sterile Products
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.3 Semi-solids 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.2	Non-sterile products
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.4	Other products or manufacturing activity (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), herbal or homeopathic products, bulk or total manufacturing, etc).
	1.4.2 Sterilisation of active substances: 1.4.2.4 Chemical
1.5	Packaging
	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 1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate: NONE

Done in Sofia on 23th of March, 2026

3/25/2026

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DR. KRASIMIR KOLEV
DEPUTY EXECUTIVE DIRECTOR
Signed by: KRASIMIR KOLEV KOLEV