



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

Certificate No: 141/2021/GMP

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

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC as amended
The competent authority of Republic of Bulgaria confirms the following:

The manufacturer: **Ukrvetprompostach**

Site address: **23-A Helsinska group Street, Brovary 07403, Kyiv region, Ukraine**

has been inspected under the inspection programme of the Bulgarian food safety agency in connection with manufacturing/importation authorisation № 25/12.04.2012, issued to "SAM BS" EOOD company, (situated at the address: Bulgaria, Sofia 1335, 25 Petar Dertliev blvd., Trade Center Labirint, office 6, fl. 3), in accordance with Art. 44 of Directive 2001/82/EC/, transposed in the national legislation by Art. 343 and 355 of the Veterinary Act, 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 **11. 11. 2021**, 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.

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 EudraGMP. If it does not appear, please contact the issuing authority.

Done in Sofia on 6th of January, 2022

PROF. DR. HRISTO DASKALOV, DVM
EXECUTIVE DIRECTOR

Bulgarian Food Safety Agency
Ministry of Agriculture
Sofia, Bulgaria



¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMP database.

³ These requirements fulfil the GMP recommendations of WHO.

✉ Sofia, 1606, "Pencho Slaveikov" blvd. 15A

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Part 2
Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS *	
<p>- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary.</p> <p>- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;</p> <p>- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.</p>	
1.1	Sterile Products
	<p><i>1.1.1 Aseptically prepared</i> (processing operations for the following dosage forms)</p> <p>1.1.1.4 Small volume liquids</p>
1.2	Non-sterile products
	1.2.1.17 Other non-sterile medicinal product <Blister with antigen inserted into edible bait >
1.3	Biological medicinal products
	<p><i>1.3.1 Biological medicinal products</i></p> <p>1.3.1.2 Immunological products</p>
1.6	Quality control testing
	<p>1.6.1 Microbiological: sterility</p> <p>1.6.2 Microbiological: non-sterility</p> <p>1.6.3 Chemical/Physical</p> <p>1.6.4 Biological</p>

Any restrictions or clarifying remarks related to the scope of this certificate:
 This certificate applies to immunological veterinary medicinal products specified in Manufacturing Authorisation No 25/12.04.2012, issued to "SAM BS" EOOD

Done in Sofia on 6th of January, 2022

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