REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE, FOOD AND FORESTRY
BULGARIAN FOOD SAFETY AGENCY

Certificate No 128/2021/GMP

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
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: **FM Pharm Ltd**
Site address: **Sencanski put bb 24000, Subotica, Serbia.**
Has been inspected under the national inspection programme and in connection with manufacturing authorisation No. 34/14.12.2017 issued to **DSM DENITRANS LTD** company, located at the address: Razgrad, 11 Neofit Rilski Str., Bulgaria, 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 1-nd 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 **24-26.11.2020**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC[3].
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 11th of January, 2021

PROF. DR. PASKAL ZHELYAZKOV, PhD
EXECUTIVE DIRECTOR
Bulgarian Food Safety Agency
Ministry of Agriculture, Food and Forestry
Sofia, Bulgaria

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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.

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Part 2

☐ Human Medicinal Products ☒ Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS

- 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 thecontrary.
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- 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.

1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.8 Other solid dosage forms – powder
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate:
This certificate applies to veterinary medicinal products specified in Manufacturing Authorisation N 34 of 14.12.2017 issued to DSM DENITRANS LTD.
The quality control tests under 1.6. also apply to the production of liquid sterile and non-sterile VMPs in the FM PHARM LTD site with a location Beli Golub 20, 24413 Palic, Serbia.

Done in Sofia on 11th of January, 2021

PROF. DR. PASKAL ZHELYAZKOV, PhD
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