MINISTRY OF AGRICULTURE AND FOOD

BULGARIAN FOOD SAFETY AGENCY

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Certificate No: 46/2015/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: **Idol Ilac Dolum Sanayi ve Tic. AS**

Site address: **Davutpasa Mh. Cebealibey sk. No 20 34010 Zeytinburnu, Istanbul, Turkey;**

Has been inspected in order a Manufacturing Authorisation to be issued to TERRAFARM-BG LTD company, (situated at the address: 3, "Batova" Str., 9000 Varna, Bulgaria)
in accordance with Art. 44 of Directive 2001/82/EC/, transposed in the national legislation by Art. 343 and 355 (Veterinary Act, enforced on 2-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 **19. 02. 2015** it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Community and *[MRA partner]*/The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.
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, after which time the issuing authority should be consulted.The authenticity of this certificate may be verified with the issuing authority.

Done in Sofia on ....., 2015

BULGARIAN FOOD SAFETY AGENCY

PROF. PLAMEN MOLLOV
EXECUTIVE DIRECTOR
Bulgarian Food Safety Agency
Ministry of Agriculture and Food
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 These requirements fulfil the GMP recommendations of WHO.

Part 2
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 the contrary. 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.

1.1	**Sterile products**
	1.1.1 Aseptically prepared (list of dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
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 covers the production of veterinary medicinal products in accordance with manufacturing /importation authorization of veterinary medicinal products № 29 from 12. 03. 2015, issued to TERRAFARM-BG Ltd., Varna, Bulgaria.

Done in Sofia on ....., 2015

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