

Certificate of Analysis

Product: **Mastijet Forte 8x20inj 299**
Batch: **A452A02**

INTERVET INTERNATIONAL BV
Wim de Körverstraat 35
P.O. Box 31, 5830 AA BOXMEER
NETHERLANDS



Country: Distribution via Lithuania

Sales Order Number: 1105891937 / 10
Delivery Number: 1207418778 / 900002
Strength: 200mg/Tetracycline HCl per syringe 8 g
250mg/Neomycine base (as sulfate) per syringe 8 g
2000 IU Bacitracin per syringe 8 g
10mg/Prednisolone per syringe 8 g

Pharmaceutical Form: oily suspension for intramammary use

Material Number: 147727
Type of Container: PE injector
Manufacturing Date: 04-Jan-2018
Storage Conditions: 2-8°C

Package Size: 8 GR
Expiry Date: Dec-2019



CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

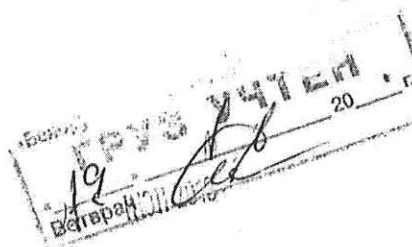
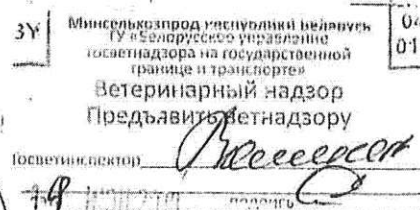
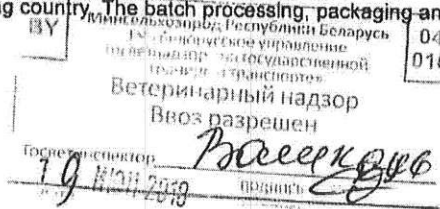
This batch has been released for: BY

Name: A. van Drunen

Function:

Date: 30 MAY 2018

Signature: Qualified Person



Vykdomasis direktorius
Mindaugas Malinauskas

Certificate of Analysis

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Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Appearance of Suspension- color		Yellow	Yellow
Appearance of Suspension- physical state		Oily Suspension	Oily Suspension
Content Tetracycline HCL		190 - 210 mg/8 g	198 mg/8 g
Content Neomycin Base HPLC		237 - 262 mg/8 g	252 mg/8 g
Content Bacitracin		1900 - 2200 IU/8g	2040 IU/8g
Content Prednisolone		9.5 - 10.5 mg/8 g	10.3 mg/8 g
Identification Tetracycline HCL		Positive	Positive
Identification Neomycin HPLC		Positive	Positive
Identification Bacitracin		Positive	Positive
Identification Prednisolone		Positive	Positive
Syringeability		Expellable within 15 sec	Expellable within 15 sec
Sterility	Ph. Eur. 2.6.1.	Sterile	Sterile
Deliverable Volume/Mass		7.2 - 8.8 g/SYG	8.0 g/SYG

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