

Certificate of Analysis

Product: **DEXAFORT, 1X50 ML**
Batch: **A090A01**



Country: **Hungary**
Sales Order Number: **1103103138 / 10**
Delivery Number: **1203920878 / 900001**
Strength: **Dexamethasone 3 mg/ml**
Pharmaceutical Form: **suspension for injection**

Material Number:
020154
Type of Container: **Glass vials, type I** Package Size: **50 ML**
Manufacturing Date: **10-Jan-2014** Expiry Date: **Dec-2016**
Storage Conditions:
15-25°C

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.

Name:
Function:
Date:
Signature:

P.G. Mooren
Qualified Person
26 MAR 2014


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



Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Appearance-Color		White to Off White	White to Off-White
Appearance-Physical State		Suspension	Suspension
Color		≤ B7	≤ B7
Contents on Average		> 50.0 mL	51.1 mL
pH	Ph. Eur. 2.2.3	7.0 - 7.8	7.3
Iden. Dexamethasone Phenyl Propionate		Positive	Positive
Iden. Dexamethasone Sodium Phosphate		Positive	Positive
Identity Benzylalcohol		Positive	Positive
Content Dexamethasone Phenylpropionate		2.54 - 2.80 mg/mL	2.76 mg/mL
Content Dexamethasone Sodium Phosphate		1.25 - 1.39 mg/mL	1.35 mg/mL
Content Benzyl Alcohol		9.4 - 11.5 mg/mL	10.2 mg/mL
Rel. Substances, Dexamethasone free		≤ 40.0 µg/mL	0.5 µg/mL
Rel. Substances, Total Related		≤ 1.5 %	0.1 %
Rel. Substances, Unknown, Single		≤ 0.5 %	0.0 %
Rel. Substances, Benzaldehyde		≤ 10 µg/mL	0 µg/mL
Redispersability		≤ 30 Seconds	≤ 30 Seconds
Syringeability		Expellable through 21G Needle	Expellable through 21G Needle
Particle Size: 90 % ≤ 5 µm		Complies	Complies
Particle Size: 99 % ≤ 30 µm		Complies	Complies
Sterility		Sterile	Sterile