Intervet International GmbH
Feldstraße 1a
85716 UNTERSCHLEISSHEIM
GERMANY

Certificate of Analysis

Product: ***Zuprevo 40 mg/ml 1x100ml 564***
Batch: ***A132A01***

MSD Animal Health

Country:	Hungary
Sales Order Number:	**1103594347 / 10**
Delivery Number:	**1204562612 / 900001**

Material Number:
117706

Package Size:
100 ML

Manufacturing Date:
22-Oct-2014

Expiry Date:
Sep-2016

Storage Conditions:
Below 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:

This document has been created electronically and is valid without signature

Anke Andres, Qualified Person

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Results of Analysis

Test	Method	Specification	Result
Characters - Color	Visual Examination	Yellowish	Complies
Characters - Physical State	Visual Examination	Solution	Complies
Appearance of solution - clarity	Ph. Eur. 2.2.1.	Clear	Complies
Appearance of solution - color	Ph. Eur. 2.2.2.	< Y4 or < BY4	Complies
pH	Ph. Eur. 2.2.3	5.0 - 6.0	5.5
Particulate Contamination	Ph. Eur. 2.9.20.	Practically Free from Visible Particles	Complies
Identification PMT and PMT-T A	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification PMT and PMT-T B	UV-Spectrum with HPLC-PDA	PDA Spect.of the Correspond.Peaks Comply	Complies
Assay PMT and PMT-T	HPLC	38.0 - 42.0 mg/mL	40.1 mg/mL
Deg. prod., S-trans PMT	HPLC	≤ 0.8 %	0.1 %
Deg. prod., unspecified	HPLC	≤ 1.0 %	0.2 %
Deg. prod., total	HPLC	≤ 3.0 %	0.5 %
Deg. prod., RO-PMT	HPLC	≤ 0.8 %	0.0 %
Bacterial Endotoxins	USP Test Method < 85 >, Ph. Eur. 2.6.14	< 50 IU/ml	Complies
Sterility	USP Test Method < 71 > , Ph. Eur. 2.6.1	No Growth Detectable	Complies
Fill Volume	Weight Measurement	≥ 102.0 mL	103.9 mL