

Certificate of Analysis

Product: **Dexadreson 1x50ml 290**
Batch: **A164A01**



Country: **Hungary**
Sales Order Number: **1103313070 / 10**
Delivery Number: **1204349154 / 900001**

Material Number:
078887
Type of Container: **Vial** Package Size: **50 ML**
Manufacturing Date: **06-Oct-2014** Expiry Date: **Sep-2017**
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:

Anke Andres, Qualified Person

**This document has been
created electronically
and is valid without signature**

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Product: *Dexadreson 1x50ml 290*

Batch: *A164A01*

Results of Analysis



MSD

Animal Health

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Characters - Color	Visual Examination	Colorless	Complies
Characters - Physical State	Visual Examination	Solution	Complies
Characters - Clarity	Visual Examination	Clear	Complies
Particulate Contamination	Ph. Eur. 2.9.20.	Practically Free from Visible Particles	Complies
Appearance of Solution	Ph. Eur. 2.2.2.	≤ B9	Complies
pH	Ph. Eur. 2.2.3	7.0 - 7.8	7.5
ID Dexamethasone Sodium Phosphate	HPLC	Rt of the Corresponding Peaks Comply	Complies
ID Dexamethasone Sodium Phosphate	UV-Spectrum with HPLC-PDA	PDA Spect.of the Correspond.Peaks Comply	Complies
Identification Benzyl Alcohol	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification Benzyl Alcohol	UV-Spectrum with HPLC-PDA	PDA Spect.of the Correspond.Peaks Comply	Complies
Assay Dexamethasone Sodium Phosphate	HPLC	2.50 - 2.76 mg/mL	2.62 mg/mL
Assay Benzyl Alcohol	HPLC	14.0 - 17.2 mg/mL	15.7 mg/mL
Rel. Substances, Benzaldehyde	HPLC	≤ 0.1 %	0.0 %
Rel. Substances Dexamethasone	HPLC	≤ 1.0 %	0.0 %
Rel. Substances, Unknown, Single	HPLC	≤ 0.5 %	0.1 %
Rel. Substances, Sum	HPLC	≤ 1.5 %	0.2 %
Sterility	Ph. Eur. 2.6.1.	No Growth Detectable	Complies
Fill Volume	Weight Measurement	≥ 50.0 mL	50.5 mL