

Certificate of Analysis

Product: Cobactan LA 7,5% 1x100ml 290
Batch: A170A01



Country: Hungary
Sales Order Number: 1103081663 / 10
Delivery Number: 1203906437 / 900001

Material Number:
092181
Type of Container: Vial
Package Size: 100 ML
Manufacturing Date: 18-Oct-2013
Expiry Date: Sep-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:

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

Dr. Susanne Jost, Qualified Person

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Results of Analysis



<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Characters - Color	Visual Examination	White to Off White	Complies
Characters - Physical State	Visual Examination	Suspension	Complies
Characters - Physical State	Visual Examination	Pract. Free from Visible Contamination	Complies
Density	Ph. Eur. 2.2.5.	0.97 - 1.01 g/cm ³	0.98 g/cm ³
Water	Karl Fischer	≤ 1 %	0 %
Sedimentation	Visual Examination	No Sediment	Complies
Particle Size Distribution d (0,9)	Laser Diffraction	≤ 20 µm	14 µm
Particle Size Distribution d (0,99)	Laser Diffraction	≤ 75 µm	23 µm
Viscosity	Ph. Eur. 2.2.10.	0.040 - 0.150 Pa*s	0.076 Pa*s
Identification Cefquinome	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification Cefquinome	UV-Spectrum with HPLC-PDA	PDA Spect. of the Correspond. Peaks Comply	Complies
Rel. Substances, 2,3-Cyclohexenpyridine	HPLC	≤ 1.0 %	0.3 %
Rel. Substances, Others, Single	HPLC	< 1.0 %	Complies
Rel. Substances, Sum	HPLC	≤ 2.0 %	1.6 %
Assay Cefquinome	HPLC	71.3 - 78.7 mg/mL	76.9 mg/mL
Fill Volume	Weight Measurement	≥ 103.0 mL	104.3 mL
Bacterial Endotoxins	USP Test Method < 85 >, Ph. Eur. 2.6.14	< 75 IU / ml	Complies
Sterility	USP Test Method < 71 >, Ph. Eur. 2.6.1	No Growth Detectable	Complies