

Certificate of Analysis

Product: Cobactan 2,5% 1x100ml 290
Batch: A694A01

Country: Hungary
Sales Order Number: 1103499485 / 10
Delivery Number: 1204444130 / 900001



Material Number:
711113

Package Size:
100 ML

Manufacturing Date: **19-Nov-2014**
Expiry Date: **Oct-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**

Anke Andres, Qualified Person



Certificate of Analysis

Product: **Cobactan 2,5% 1x100ml 290**
 Batch: **A694A01**

Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Characters - Color	Visual Examination	Milky-White to Slight Brownish	Complies
Characters - Physical State	Visual Examination	Suspension	Complies
Identification Cefquinome	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification Sulphate	Ph. Eur. 2.3.1.	Gives Reaction of Sulphate	Complies
Water	Ph. Eur. 2.5.12.	≤ 0.2 %	0.1 %
Degrad. Prod. 2,3-Cyclohexenopyridine	HPLC	≤ 1.5 %	0.4 %
Degrad. Prod. Unspecified, identified	HPLC	≤ 0.7 %	0.3 %
Degrad. Prod. Unspecified, unidentified	HPLC	≤ 0.3 %	0.1 %
Degrad. Prod. sum	HPLC	≤ 2.5 %	1.4 %
Assay Cefquinome	HPLC	23.75 - 26.25 mg/mL	25.38 mg/mL
Sedimentation	Visual Examination	No Sediment	Complies
Fill Volume	Weight Measurement	≥ 100 mL	101 mL
Particle Size Distribution d (0,9)	Laser Diffraction	≤ 20 µm	12 µm
Particle Size Distribution d (0,99)	Laser Diffraction	≤ 75 µm	21 µm
Resuspendability	Visual Examination	No Agglomerates and Sediment	Complies
Sterility	Ph. Eur. 2.6.1.	No Growth Detectable	Complies
Bacterial Endotoxins	Ph. Eur. 2.6.14.	≤ 2.5 IU / ml	Complies