

Certificate of Analysis

Product: Cobactan LC 15x1inj 290
Batch: B015A01

Country: **Hungary**

Sales Order Number: **1103129356 / 10**
Delivery Number: **1203934722 / 900001**



Material Number:
705278

Type of Container: **Injector** Package Size: **8 GR**

Manufacturing Date: **23-Jan-2014** Expiry Date: **Jun-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:

Dr. Susanne Jost, Qualified Person

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

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Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Characters - Injector	Visual Examination	White, Opaque Plastics	Complies
Characters - Injector Exterior	Visual Examination	No Leaked Oil	Complies
Characters - Color	Visual Examination	White to Slightly Yellow	Complies
Characters - Physical State	Visual Examination	Oily, Viscous, Homogeneous Ointment	Complies
Identification Cefquinome	HPLC	Rt of the Corresponding Peaks Comply	Complies
Extractable Weight	Weight Measurement	8.0 - 8.8 Gram	8.2 Gram
Rel. Substances, 2,3-Cyclohexenpyridine	HPLC	≤ 1.0 %	0.4 %
Rel. subst. Unspecified, identified	HPLC	≤ 0.7 %	0.3 %
Rel. subst. Unspecified, unidentified	HPLC	≤ 0.3 %	0.1 %
Rel. Substances, Sum	HPLC	≤ 3.0 %	1.2 %
Aggregates	Light Microscopy	No Visible Aggregates Present	Complies
Viscosity	Rotating Viscosimeter	0.1 - 0.2 Pa*s	0.2 Pa*s
Particle Size ≤ 5 μm	Light Microscopy	≥ 80 %	Complies
Particle Size ≤ 10 μm	Light Microscopy	≥ 90 %	Complies
Particle Size ≤ 20 μm	Light Microscopy	≥ 95 %	Complies
Particle Size ≤ 50 μm	Light Microscopy	≥ 100 %	Complies
Assay Cefquinome, Extractable Weight	HPLC	71.25 - 78.75 mg/D	76.11 mg/D
Sterility	Ph. Eur. 2.6.1.	No Growth Detectable	Complies