

Certificate of Analysis

Product: Ceporex Inj. 1x100ml 290
Batch: A118A02



Country: **Hungary**
Sales Order Number: **1103074385 / 10**
Delivery Number: **1203873103 / 900001**

Material Number:
055940

Package Size:
100 ML

Manufacturing Date: **11-Apr-2013**
Expiry Date: **31-Mar-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

Certificate of Analysis

Product: **Ceporex Inj. 1x100ml 290**
Batch: **A118A02**

Intervet International GmbH
Feldstraße 1a
85716 UNTERSCHLEISSHEIM
GERMANY



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
Identification A	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification B	UV-Spectrum with HPLC-PDA	PDA Spect. of the Correspond. Peaks Comply	Complies
Fill Volume	Weight Measurement	≥ 100 mL	104 mL
Assay Cephalixin	HPLC	171 - 189 mg/mL	185 mg/mL
Syringe Test	Physical Test	Complies	Complies
Particle size distribution d (1.0)	Light Microscopy	≤ 250 µm	Complies
Redispersion	Visual Examination	Suspension	Complies
Bacterial Endotoxins	Ph. Eur. 2.6.14	≤ 125.00 IU/mL	Complies
Sterility	Ph. Eur. 2.6.1.	No Growth Detectable	Complies