

Certificate of Analysis

Product: **Metricure 1x12inj 290**
Batch: **A129A01**



Country: **Hungary**

Sales Order Number: **1103623926 / 10**
Delivery Number: **1204519950 / 900010**
Strength: **Cefapirin 0,5 gr**
Pharmaceutical Form: **intrauterine suspension**

Material Number:
105038

Type of Container: **PE injector**
Package Size: **19 GR**

Manufacturing Date: **02-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:

P.G. Mooren
Qualified Person
23 MAR 2015

A handwritten signature in blue ink, appearing to read "P.G. Mooren", is written over the bottom portion of the certification stamp.

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Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Appearance-Color		Creamy	Creamy
Appearance-Physical State		Oily Suspension	Oily Suspension
Identity Cephapirin		Positive	Positive
Identity Benzathine		Positive	Positive
Content Cephapirin		475 - 525 mg/19 g	509 mg/19 g
Content Benzathine		20.0 - 24.0 %	21.6 %
Rel. Compounds, Total impurities		≤ 3.5 %	2.0 %
Rel. Compounds, Desacetyl-Cephapirin		≤ 1.5 %	0.8 %
Rel. Compounds, Desacetoxy-Cephapirin		≤ 2.0 %	0.6 %
Related Compounds, Total Unknown		≤ 1.5 %	0.5 %
Rel. Compounds, individual Unknown		≤ 0.5 %	0.1 %
Particle Size d(0.5)		≤ 25 µm	6 µm
Particle Size d(0.9)		≤ 50 µm	28 µm
Syringeability		≤ 15 Seconds (No Interruptions)	≤ 15 Seconds (no Interruptions)
Viscosity		50 - 300 mPa•s	94 mPa•s
Deliverable Mass		19.0 - 20.0 g/INJ	19.1 g/INJ
Water content		≤ 0.5 %	0.1 %
Uniformity of Dosage Units	Ph. Eur. 2.9.40	Conform	Conform
Sterility		Sterile	Sterile

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