

CERTIFICATE OF ANALYSIS

Product **CEFOTAXIME SODIUM**

Product number C0111 011690 Batch number Date of manufacturing : xx-10-2015 Date of expiry 31-03-2018

Packaging and storage store at 2 - 8°C in well-closed containers

Description Identification Clarity and colour of solution	SPECIFICATION almost white crystalline powder conform clear and $A_{430} < 0.20$	RESULT complies complies clear and $A_{430} = 0.060$	UNITS	REMARKS 10% in H ₂ O
Specific rotation	+58 – +64	+61.54	0	dried substance
рН	4.5 - 6.5	5.58		10% in H ₂ O
Loss on drying	≤ 3.0	2.26	%	3h, 105°C
Chromatographic purity:				HPLC
- any individual impurity	≤ 1.0	0.34	%	
- sum of all impurities	≤ 3.0	1.98	%	
Assay	916 – 964	939	μg/mg	dried substance

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by: drs. M. van Wissen, pharmacist

Department of Quality Control Duchefa B.V.

Date: 24-11-2015

The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.

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