

CERTIFICATE OF ANALYSIS

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

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

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	almost white crystalline powder	complies		
Identification	conform	complies		
Clarity and colour of solution	clear and $A_{430} < 0.20$	clear and $A_{430} = 0.060$		10% in H ₂ O
Specific rotation	+58 – +64	+61.54	°	dried substance
pH	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

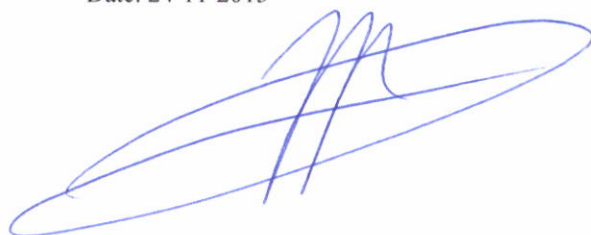
This certificate of analysis is conform the results of the manufacturer.

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.