

CERTIFICATE OF ANALYSIS

Product : **TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1**
 Product number : T0190
 Batch number : 012504
 Date of production : xx-09-2016
 Date of expiry : 30-09-2018

Packaging and storage : store dry at 2 – 8 °C, this product is hygroscopic

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	white to yellowish powder	complies		
Identification	conform	complies		HPLC
Solubility	clear colourless solution	complies		
Water	≤ 4.2	2.5	%	Karl Fischer
Assay clavulanic acid	≥ 50	55.0	µg/mg	dried substance
Assay ticarcillin	≥ 750	827.0	µg/mg	dried substance
Related substances				
- Impurity A	< 4.0	0.40	%	
- Impurity B	< 2.5	0.39	%	
Bacterial endotoxins	< 0.07	complies	EU/mg	
Particulate matter	conform	complies		

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: 07-11-2016



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