

CERTIFICATE OF ANALYSIS

Product : **TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1**
 Product number : T0190
 Batch number : 014455
 Date of production : xx-01-2019
 Date of expiry : 31-01-2021

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	2.3	%	Karl Fischer
pH	5.5 – 7.5	6.4		
Assay clavulanic acid	≥ 50	56.0	µg/mg	dried substance
Assay ticarcillin	≥ 750	828.0	µg/mg	dried substance
Related substances:				
- Impurity A	< 4.0	0.30	%	
- Impurity B	< 2.5	0.30	%	
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. Q. de Hoog, pharmacist
 Department of Quality Control Duchefa B.V.

Date: 02-04-2019

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