

CERTIFICATE OF ANALYSIS

Product : **TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1**
 Product number : T0190
 Batch number : 013402
 Date of production : xx-06-2017
 Date of expiry : 30-06-2019

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 colorless solution	complies		
Water	≤ 4.2	2.4	%	Karl Fischer
pH	5.5 – 7.5	6.5		
Assay clavulanic acid	≥ 50	52.0	µg/mg	dried substance
Assay ticarcillin	≥ 750	822.0	µg/mg	dried substance
Related substances:				
- Impurity A	< 4.0	0.81	%	
- Impurity B	< 2.5	0.41	%	
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:

p/b drs. M. van Wissen, pharmacist
 Department of Quality Control Duchefa B.V.

Date: 29-12-2017


 U. Kong Tse Lam

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