

CERTIFICATE OF ANALYSIS

Product TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1

Product number T0190 Batch number 015535 Date of production xx-05-2020 Date of expiry 31-05-2022

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

Dec. 1.d	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
pН	5.5 - 7.5	6.5		
Assay clavulanic acid	≥ 50	55.0	μg/mg	dried substance
Assay ticarcillin	≥ 750	828.0	μg/mg	dried substance
Related substances:				
- Impurity A	< 4.0	0.56	%	
- Impurtiy B	< 2.5	0.46	%	
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: 29-06-2020

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