

CERTIFICATE OF ANALYSIS

Product : TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1

 Product number
 : T0190

 Batch number
 : 017938

 Date of production
 : xx-04-2023

 Date of expiry
 : 30-04-2026

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

| Description Identification Solubility | SPECIFICATION white to yellowish powder conform clear colourless solution | RESULT complies complies complies | UNITS | REMARKS hygroscopic HPLC |
|---------------------------------------------|------------------------------------------------------------------------------------|--------------------------------------------|-------|--------------------------------|
| Water | ≤ 4.2 | 1.7 | % | Karl Fischer |
| рН | 5.5 - 7.5 | 6.7 | | |
| Assay clavulanic acid | ≥ 50 | 55.0 | μg/mg | dried substance |
| Assay ticarcillin | ≥ 7 50 | 824.0 | μg/mg | dried substance |
| Related substances: | | | , 0 0 | |
| - Impurity A | < 4.0 | 0.37 | % | |
| - Impurtiy B | < 2.5 | 0.37 | % | |
| 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: 19-01-2023

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