



CERTIFICATE OF ANALYSIS

Product : **TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1**
Product number : T0190
Batch number : 018983
Date of production : xx-10-2024
Date of expiry : 31-10-2026

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

| | SPECIFICATION | RESULT | UNITS | REMARKS |
|-----------------------|---------------------------|---------------|--------------|-----------------|
| Description | white to yellowish powder | complies | | hygroscopic |
| Identification | conform | complies | | HPLC |
| Solubility | clear colourless solution | complies | | |
| Water | ≤ 4.2 | 1.9 | % | Karl Fischer |
| pH | 5.5 – 7.5 | 6.8 | | |
| Assay clavulanic acid | ≥ 50 | 57.0 | µg/mg | dried substance |
| Assay ticarcillin | ≥ 750 | 835.0 | µg/mg | dried substance |
| Related substances: | | | | |
| - Impurity A | < 4.0 | 0.45 | % | |
| - Impurity B | < 2.5 | 0.44 | % | |
| 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:

Date: 08-01-2025

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Department of Quality Control Duchefa B.V.

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

Duchefa Biochemie B.V.