

CERTIFICATE OF ANALYSIS

Product : **TICARCILLIN DISODIUM / CLAVULANATE POTASSIUM 15:1**
 Product number : T0190
 Batch number : 019431
 Date of production : xx-06-2025
 Date of expiry : 30-06-2027

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 | 6.7 | | |
| Assay clavulanic acid | ≥ 50 | 54.0 | µg/mg | dried substance |
| Assay ticarcillin | ≥ 750 | 834.0 | µg/mg | dried substance |
| Related substances: | | | | |
| - Impurity A | < 4.0 | 0.42 | % | |
| - Impurity B | < 2.5 | 0.42 | % | |
| 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:

Q. de Hoog, MSc, pharmacist
 Department of Quality Control Duchefa Biochemie B.V.

Date: 06-08-2025

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

Duchefa Biochemie B.V.