

## Certificate of Analysis

**Productname:** Bacitracinum micronisatum  
**Number of analysis/Inspection Code:** 1 / KEUR-187207B  
**Batchnumber:** 20E14-F01-373256  
**Reference code / No.:** 3697 / C2280138  
**Analysed according to:** PHEUR10.2+

| Tests                               | Requirement                                  | Result  | Unit  | Standard remark          |
|-------------------------------------|--|---------|-------|--------------------------|
| Fermentation                        | Conform                                      | Conform |       | Data producer            |
| Particle size                       | 99% <50 µm                                   | Conform |       | Microscopy               |
| Identification B                    | Conform                                      | Conform |       | Composition              |
| Identification C                    | Conform                                      | Conform |       |                          |
| Appearance of solution              | Clear  | Conform |       | 1% <i>m/V</i>            |
| Absorbance at 420 nm                | <=0,45                                       | 0,12    |       |                          |
| pH                                  | 6,0 - 7,0                                    | 6,3     |       | 1% <i>m/V</i>            |
| Composition                         | Conform                                      | Conform |       | HPLC                     |
| Bacitracin A                        | >=45,0                                       | 53,0    | %     |                          |
| Sum of bacitracins A, B1, B2 and B3 | >=77,0                                       | 80,8    | %     |                          |
| Related substances                  | Conform                                      | Conform |       | HPLC                     |
| Sum of impurities L and N           | <=8,0  | 5,5     | %     |                          |
| Impurity E                          | <=4,0  | 0,8     | %     |                          |
| Impurity A                          | <=3,5  | 2,2     | %     |                          |
| Impurity B                          | <=3,0  | 1,8     | %     |                          |
| Impurity M                          | <=3,0  | 0,8     | %     |                          |
| Impurity C                          | <=2,5  | 1,5     | %     |                          |
| Sum of impurities O,P and Q         | <=2,5  | 0,9     | %     |                          |
| Sum impurities F and G              | <=2,0  | <0,25   | %     |                          |
| Impurity H                          | <=1,0  | <0,25   | %     |                          |
| Any other impurity                  | <=2,0  | 1,4     | %     |                          |
| Total impurities                    | <=23,0                                       | 19,2    | %     |                          |
| Loss on drying                      | <=5,0  | 0,3     | %     | 3 h 60°C vacuum          |
| Sulphated ash                       | <=1,0  | 0,1     | %     |                          |
| Metallic residues                   | CHMP/ICH/353369/2013                         | Conform |       | Data producer            |
| Residual solvents                   | CHMP/ICH/82260/2006                          | Conform |       | Data producer            |
| Assay Bacitracin                    | >=60   | 76      | IU/mg | Dried; data producer     |
| Assay Bacitracin                    |  | 75      | IU/mg | Not dried; data producer |
| TSE/BSE-statement:                  | No contamination with TSE/BSE-risk materials | Conform |       | Data producer            |



Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:

Paul Hofman

Pharmacist - Qualified Person

11/23/20

Expiration: 12-2023

Conclusion: APPROVED

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