

Certificate of Analysis

Productname: Bacitracinum micronisatum
Number of analysis/Inspection Code: 1 / KEUR-187179B
Batchnumber: 20E14-F01-373255
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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