

## Certificate of Analysis

**Productname:** Amoxicillinum trihydricum  
**Number of analysis/Inspection Code:** 1 / KEUR-198525B  
**Batchnumber:** 23K02-LP01  
**Reference code / No.:** 3417 / V352877  
**Analysed according to:** PHEUR11.3

| Tests                     | Requirement                                  | Result  | Unit | Standard remark    |
|---------------------------|----------------------------------------------|---------|------|--------------------|
| Appearance                | (Almost) white, crystalline powder           | Conform |      |                    |
| Identification A          | Conform                                      | Conform |      | IR-spectrum        |
| pH                        | 3,5 - 5,5                                    | 4,8     |      | 0.2%m/V            |
| Specific optical rotation | +290 - +315                                  | +294    |      | 0,2%m/V; anhydrous |
| Related substances        | Conform                                      | Conform |      | HPLC               |
| Any impurity              | <=1                                          | <1      | %    |                    |
| Dimethylaniline           | <=20                                         | Conform | ppm  | GC                 |
| Water (Karl Fischer)      | 11,5 - 14,5                                  | 13,0    | %    |                    |
| 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 Amoxicillin         | 95,0 - 102,0                                 | 101,0   | %m/m | Anhydrous          |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials | Conform |      | Data producer      |
| Nitrosamine impurities    | Art. 5(3) of Reg. (EC) No 726/2004           | Conform |      | Data producer      |

Analysis performed by the authorized laboratory LelyPharma BV.

**Manufacturer / Country** : DSM Deretil / ES  
**CEP** : R1 CEP 2001-367-Rev 05

Release:  
Anthony Amoureux  
Qualified Person

10-01-24

Expiration: 31-07-27

Conclusion: APPROVED

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