

## Certificate of Analysis

Productname: **Dexpanthenolum**

Inspection No: H04497/0520/536  
 Batchnumber: **20D16-T16-079844**  
 Expiration date: 22.01.2023  
 Analysed according to: ČL 2017, Ph.Eur.10.0  
 Original Manuf. Date: 23.1.2020

Sample Unit: 0 x  
 Batch Size: 600 x 25 g

Identification of producer: V01538  
 Batch no. of vendor: TL02001009

|                           | Requirement                                                                                                     | Result  | Unit  | Standard remark                       | Insp. Site    |
|---------------------------|-----------------------------------------------------------------------------------------------------------------|---------|-------|---------------------------------------|---------------|
| CHARACTERS                |                                                                                                                 |         |       |                                       |               |
| Appearance                | A colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white, crystalline powder. | Conform |       |                                       | Fagron CZ     |
| Solubility                | Conform                                                                                                         | Conform |       |                                       | Fagron CZ     |
| IDENTIFICATION            |                                                                                                                 |         |       |                                       |               |
| Identification A          | +29,0 - +32,0                                                                                                   | +30,1   |       | Specific optical rotation (anhydrous) | Fagron CZ     |
| Identification B          | Conform                                                                                                         | Conform |       | IR-spectrum                           | Fagron CZ     |
| TESTS                     |                                                                                                                 |         |       |                                       |               |
| Appearance of solution    | Clear / ≤B6                                                                                                     | Conform |       | 5% m/V                                | Fagron CZ     |
| pH                        | ≤10,5                                                                                                           | 9,92    |       | 5% m/V                                | Fagron CZ     |
| Specific optical rotation | +29,0 - +32,0                                                                                                   | +30,1   |       | anhydrous                             | Fagron CZ     |
| 3-Aminopropanol           | ≤0,5                                                                                                            | ≤0,5    | %     | TLC                                   | Fagron CZ     |
| Water                     | ≤1,0                                                                                                            | 0,29    | %     | Karl Fischer                          | Fagron CZ     |
| Sulfated ash              | ≤0,1                                                                                                            | 0,0     | %     |                                       | Fagron CZ     |
| Microbiology              | Conform                                                                                                         | Conform |       |                                       | Contract Lab  |
| TAMC                      | ≤2 x 10 <sup>3</sup>                                                                                            | Conform | CFU/g |                                       | Contract Lab  |
| TYMC                      | ≤2 x 10 <sup>2</sup>                                                                                            | Conform | CFU/g |                                       | Contract Lab  |
| TSE/BSE                   | No contamination with TSE/BSE-risk materials.                                                                   | Conform |       |                                       | Data Producer |
| Residual solvents         | CPMP/ICH/82 260/2006                                                                                            | Conform |       |                                       | Data Producer |
| Metallic residues         | ICH Q3D on elemental impurities                                                                                 | Conform |       |                                       | Data Producer |
| ASSAY                     |                                                                                                                 |         |       |                                       |               |
| Dexpanthenol              | 98,0 - 101,0                                                                                                    | 98,9    | %     | Anhydrous                             | Fagron CZ     |

Performed by: Lucie Kubáňová

Responsible: Mgr. Kateřina Jokešová, QC  
 PharmDr. Ivana Urbánková, QA

Date: 19.06.2020

Conclusion: **APPROVED**

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