

## Certificate of Analysis

**Productname:** Tocopherol

**Inspection No:** I08796/1221/536

**Batchnumber:** 21J01-T03-091195

**Expiration date:** 08.06.2023

**Analysed according to:** ČL 2017-Dopl.2020,Ph.Eur.10.0

**Original Manuf. Date:** 8.6.2021

**Sample Unit:** 0 x

**Batch Size:** 273 x 10 ml

**Identification of producer:** V01538

**Batch no. of vendor:** UT21060057

|                           | Requirement   | Result  | Unit  | Standard remark  | Insp. Site    |
|---------------------------|---|---------|-------|------------------|---------------|
| <b>CHARACTERS</b>         |   |         |       |                  |               |
| Appearance                | Clear, colourless or yellowish-brown, viscous, oily liquid. | Conform |       |                  | Fagron CZ     |
| Solubility                | Conform   | Conform |       |                  | Fagron CZ     |
| <b>IDENTIFICATION</b>     |   |         |       |                  |               |
| Identification A          | -0,01 - +0,01   | +0      | °     | Optical rotation | Fagron CZ     |
| Identification B          | Conform   | Conform |       | IR - spectrum    | Fagron CZ     |
| <b>TESTS</b>              |   |         |       |                  |               |
| Related substances        | Conform   | Conform |       | GC               | Contract Lab  |
| Impurity A                | ≤0,5  | 0,1     | %     |                  | Contract Lab  |
| Impurity B                | ≤1,5  | 0,4     | %     |                  | Contract Lab  |
| Sum of impurities C and D | ≤1,0  | 0,2     | %     |                  | Contract Lab  |
| Any other impurity        | ≤0,25   | 0,20    | %     |                  | Contract Lab  |
| Total impurities          | ≤2,5  | 0,9     | %     |                  | Contract Lab  |
| Microbiology              | Conform   | Conform |       |                  | Contract Lab  |
| TAMC                      | ≤2 x 10 <sup>3</sup>  | <10     | CFU/g |                  | Contract Lab  |
| TYMC                      | ≤2 x 10 <sup>2</sup>  | <10     | 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 |
| <b>ASSAY</b>              |   |         |       |                  |               |
| Alfa-tocopherol           | 96,0 - 102,0  | 100,5   | %     | GC               | Contract Lab  |

**Excipient**

|             |                            |                  |                           |                  |                  |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| <b>Name</b> | Fagron a.s. (CZ)           | <b>Address</b>   | Holická 1098/31m, Olomouc | <b>Phone No.</b> | +420585222590    |
|             | Kontrolní laboratoř č. 536 | <b>Post Code</b> | 779 00                    | <b>Fax No.</b>   | +420 585 226 521 |

The product conforms to ČL 2017-Dopl.2020,Ph.Eur.10.0.

**Performed by:** Lucie Kubáňová DiS.

**Responsible:** Ing. Pavel Mišák, QC  
MVDr. Zdenka Borská, QA

**Date:** 08.12.2021



**Conclusion:** I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

This document has been produced electronically from our quality system and is valid without signature.

|             |                            |                  |                           |                  |                  |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
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