

Certificate of Analysis

Product name:

Batch number / Weight:

Analysed according to:

Acidum ascorbicum cryst. 22A21-B05-222261 / 100 G

Ph.Eur.10

Tests Requirement Result Unit Standard remark (Almost) white, crystalline powder Conform Appearance Identification B Conform Conform Identification C 2,1 - 2,6 2,34 Appearance of solution Clear /<=BY7 Conform +20.5 - +21.5Specific optical rotation +20.9Impurity E <=0,2 <0.2 % **Related substances** Conform Conform Impurity C <=0,15 < 0,05 % Impurity D <=0,15 < 0.05 % Unspecified impurities <=0,10 < 0,05 % Total impurities other than C and <=0,2 < 0.05 % Iron <= 2,0 Conform ppm Copper <= 5.0 Conform ppm Sulphated ash <= 0,1 0,03 % Metallic residues CHMP/ICH/353369/2013 Conform Data producer CPMP/ICH/82 260/06 Data producer **Residual solvents** Conform Assay Ascorbic acid 99,0 - 100,5 99,4 %m/m **TSE/BSE-statement:** No contamination with TSE/BSE-risk materials Conform Data producer **Residual solvents** Methanol <3000 ppm

Analysis performed by the authorized lab.

Release: Agnieszka Pszczółka Qualified Person

17-08-2022

Expiration: 31-10-2024

Conclusion: APPROVED

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