

Certificate of Analysis

Product name: **Acidum ascorbicum cryst.**
Batch number / Weight: **22A21-B05-222259 / 1 KG**
Analysed according to: **Ph.Eur.10**

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | 2,1 - 2,6 | 2,34 | | |
| Appearance of solution | Clear /<=BY7 | Conform | | |
| Specific optical rotation | +20,5 - +21,5 | +20,9 | | |
| Impurity 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 D | <=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 |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| 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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