

Certificate of Analysis

Product name: **Acidum ascorbicum cryst.**
Batch number / Weight: **19J16-B01-196328 / 100 G**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------------------|----------------------------------------------|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | 2,1 - 2,6 | 2,35 | | |
| Appearance of solution | Clear /<=BY7 | Conform | | |
| Specific optical rotation | +20,5 - +21,5 | +20,8 | ° | |
| Impurity E | <=0,3 | <0,2 | % | |
| Related substances | Conform | Conform | | |
| Impurity C | <=0,15 | 0,12 | % | |
| Impurity D | <=0,15 | 0,02 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities other than C and D | <=0,2 | 0,0 | % | |
| Iron | <= 2,0 | Conform | ppm | |
| Copper | <= 5,0 | Conform | ppm | |
| Sulphated ash | <= 0,1 | 0,005 | % | |
| 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 | 99,56 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

25-03-2020

Expiration: 03-10-2021

Conclusion: APPROVED

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