

Certificate of Analysis

Product name: Zinci gluconas
Batch number / Weight: 21G12-B09-213897 / 50 G
Analysed according to: Ph.Eur.

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------------|--|---------|---------|-----------------|
| Appearance | (Almost) white crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Appearance of solution | <=ref. susp. II / <=Y6 | Conform | | |
| Sucrose and reducing sugars | Conform | Conform | | |
| Chlorides | <=500 | Conform | ppm | |
| Sulphates | <=500 | Conform | ppm | |
| Cadmium | <=2 | Conform | ppm | |
| Water (Karl Fischer) | <=12,0 | 6,95 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Zinc gluconate | 98,0 - 102,0 | 99,5 | %m/m | |
| Total aerobic microbial count (TAMC) | <=1000 | Conform | CFU / g | |
| Total yeasts and moulds (TYMC) | <=100 | Conform | CFU/g | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

09-12-2021

Expiration: 19-05-2023

Conclusion: APPROVED

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