

## Certificate of Analysis

**Product name:** **Calcii gluconas**  
**Batch number / Weight:** **20F08-B05-202322 / 250 G**  
**Analysed according to:** **Ph. Eur.**

| Tests                                | Requirement                                  | Result  | Unit    | Standard remark |
|--------------------------------------|--|---------|---------|-----------------|
| Appearance                           | White, crystalline powder                    | Conform |         |                 |
| Identification A                     | Conform                                      | Conform |         |                 |
| Identification B                     | Conform                                      | Conform |         |                 |
| Appearance of solution               | <=ref. susp. II                              | Conform |         |                 |
|                                      | Colour <=Y6                                  | Conform |         |                 |
| Organic substances and boric acid    | Conform                                      | Conform |         |                 |
| Sucrose and reducing sugars          | Conform                                      | Conform |         |                 |
| Chlorides                            | <=200  | Conform | ppm     |                 |
| Sulphates                            | <=100  | Conform | ppm     |                 |
| Magnesium and alkaline metals        | <=0,4  | 0,36    |         |                 |
| Residual solvents                    | CPMP/ICH/82 260/06                           | Conform |         | Data producer   |
| Calcium (D-)Gluconate monohydrate    | 98,5 - 102,0                                 | 99,57   | %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   |
| Metallic residues                    | CHMP/ICH/353369/2013                         | Conform |         | Data producer   |

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

10-08-2020

Expiration: 05-04-2024

Conclusion: APPROVED

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