

Certificate of Analysis

Productname: Lithii carbonas
Number of analysis/Inspection Code MON-196597B / KEUR-183974B
Batchnumber: 20F04-F07
Reference code / No.: 1229 / B542111AA
Analysed according to: PH.EUR10.2

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------|--|---------|----------|-----------------|
| Appearance | (Almost) White powder | Conform | | |
| Apparent volume | | 8,0 | ml / 5 g | |
| Identification A | Red | Conform | | Lithium |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | Carbonate |
| Appearance of solution | Clear and colourless | Conform | | 10%m/V |
| Chlorides | <=200 | Conform | ppm | |
| Sulphates | <=200 | Conform | ppm | |
| Arsenic | <=2 | Conform | ppm | |
| Calcium | <=200 | Conform | ppm | |
| Iron | <=20 | Conform | ppm | |
| Magnesium | <=150 | Conform | ppm | |
| Potassium | <=300 | Conform | ppm | |
| Sodium | <=300 | Conform | ppm | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| Assay Lithium carbonate | 98,5 - 100,5 | 100,0 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Release:
Paul Hofman
Pharmacist - Qualified Person

16-07-20

Expiration: 10-2024

Conclusion: APPROVED

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