

Certificate of Analysis

Productname:

Magnesii sulf. heptahy.cr.(PV)

Number of analysis/Inspection Code:

3 / KEUR-110408B

Batchnumber:

14B18-B01-295047

Reference code / No.:

3529 / 2213000120

Analysed according to:

PH.EUR 8.0

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGO

ZA:

Datum prejema: 24.2.15

Pregledal: MAHOLT Robert, mag. farm., spec.

Datum pregleda: 24.1.1015

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------|--|---------|------|----------------------|
| | | | | |
| Appearance | Colourless crystals or white, | Conform | | |
| | crystalline powder | Conform | | |
| Identification A | White | Conform | | Sulphate |
| Identification B | White | Conform | | Magnesium |
| Appearance of solution | Clear / colourless | Conform | | 10%m/V |
| Acidity or alkalinity | Conform | Conform | | |
| Chlorides | <=300 | Conform | ppm | Data producer |
| Arsenic | <=2 | Conform | ppm | Data producer |
| Iron | <=20 | Conform | ppm | Data producer |
| Heavy metals | <=10 | Conform | ppm | Data producer |
| Loss on drying | 48,0 - 52,0 | 50,5 | % | 110 - 400 °C |
| Residual solvents | CPMP/ICH/283/95 | Conform | | Data producer |
| Assay Magnesium sulphate | 99,0 - 100,5 | 99.8 | %m/m | Dried; data producer |
| Bacterial endotoxins | <=3 | Conform | EU/g | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| | | | | |

Analyse performed by the authorized lab Synergy Health+Microbiologie.

Release:

Drs. M.V. Garcia Alia

Pharmacist - QA Manager / QP

07/23/14

Expiration: 11-2018

Conclusion: APPROVED

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