



Certificate of Analysis

| |
|---|
| FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO |
| XA: |
| Datum prejema: 29.1.14 |
| Pregledal: MAROLT Robert, mag. farm. spec. |
| Datum pregleda: 30.1.2014 |

Productname: Dinatrii phosphas dihydricus
Number of analysis/Inspection Code: 1 / KEUR-99574B
Batchnumber: 13A14-B05-285139 ✓
Reference code / No.: 2036 / B56591A
Analysed according to: PH.EUR7.6+

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------------|--|---------|-----------------------|------------------------|
| Appearance | White, crystalline powder or colourless crystals | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | 19,5 - 21,0 | Conform | % | Loss on drying |
| Identification C | Yellow | Conform | | Phosphate |
| Identification D | Conform | Conform | | Sodium |
| Appearance of solution | Clear and colourless | Conform | | 5% <i>m</i> / <i>V</i> |
| Reducing substances | Conform | Conform | | Data producer |
| Sodium dihydrogenphosphate | Conform | Conform | % | Data producer |
| Chlorides | <= 400 | Conform | ppm | Data producer |
| Sulphates | <= 0,1 | Conform | % | Data producer |
| Arsenic | <= 4 | Conform | ppm | Data producer |
| Iron | <= 40 | Conform | ppm | Data producer |
| Heavy metals | <= 20 | Conform | ppm | Data producer |
| Loss on drying | 19,5 - 21,0 | 20,2 | % | 130 °C |
| Residual solvents | CPMP/ICH/283/95 | Conform | | Data producer |
| Disodium hydrogenphosphate dihydrate | 98,0 - 101,0 | 100,3 | % <i>m</i> / <i>m</i> | Dried; data producer |
| Endotoxins | <= 1,1 | Conform | IU / mg | LAL-test |
| 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

17-09-13

Expiration: 09-2015 ✓

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.