



Certificate of Analysis

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

ZA: *[Signature]*

Datum prejema: 20.6.14
Pregledal: VAROLT Robert, mag. farm., spec.

Datum pregleda: 23.6.14

Productname: Atropini sulfas
Number of analysis/Inspection Code: 1 / KEUR-107214B
Batchnumber: 14A15-B01-291863
Reference code / No.: 3273 / APS1311002
Analysed according to: PH.EUR 8.0

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------|--|---------|-----------------------|------------------|
| Appearance | White, crystalline powder | Conform | | |
| Identification A | -0,50 - +0,05 | Conform | ° | Optical rotation |
| Identification B | Conform | Conform | | IR-spectrum |
| Identification E | White | Conform | | Sulphate |
| pH | 4,5 - 6,2 | 5,9 | | 2% <i>m</i> /V |
| Optical rotation | -0,50 - +0,05 | -0,01 | ° | |
| Related substances | Conform | Conform | | HPLC |
| Impurity E | <=0,3 | n.d. | % | |
| Impurity H | <=0,3 | n.d. | % | |
| Impurity A | <=0,2 | 0,1 | % | |
| Impurity B | <=0,2 | 0,1 | % | |
| Impurity C | <=0,2 | n.d. | % | |
| Impurity D | <=0,2 | n.d. | % | |
| Impurity F | <=0,2 | n.d. | % | |
| Impurity G | <=0,2 | n.d. | % | |
| Unspecified impurities | <=0,10 | 0,10 | % | |
| Total impurities | <=0,5 | 0,3 | % | |
| Water (Karl Fischer) | 2,0 - 4,0 | 2,9 | % | |
| Sulphated ash | <= 0,1 | Conform | % | |
| Residual solvents | CPMP/ICH/283/95 | Conform | | Data producer |
| Assay Atropine sulphate | 99,0 - 101,0 | 100,4 | % <i>m</i> / <i>m</i> | Anhydrous |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analyse performed by the authorized lab Proxylabs.

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

04/23/14

Expiration: 11-2015

Conclusion: APPROVED