



## Certificate of Analysis

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

KA: 4

Datum prejema: 5.6.13  
Pregledal: MAROLT Robert, mag. farm., spec.

Datum pregleda: 6.6.2013

Productname: **Atropini sulfas**  
Number of analysis/Inspection Code: 1 / KEUR-93686B  
Batchnumber: **12L17-B01-279953**  
Reference code / No.:  
Analysed according to: **PH.EUR 7.6**

| 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                                    | 5,3     |              | 2% <i>m/V</i>    |
| Optical rotation        | -0,50 - +0,05                                | 0,00    | °            |                  |
| 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  | <0,05   | %            |                  |
| 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                                       | 0,08    | %            |                  |
| Total impurities        | <=0,5  | 0,2     | %            |                  |
| Water (Karl Fischer)    | 2,0 - 4,0                                    | 3,3     | %            |                  |
| Sulphated ash           | <= 0,1                                       | Conform | %            |                  |
| Residual solvents       | CPMP/ICH/283/95                              | Conform |              | Data producer    |
| Assay Atropine sulphate | 99,0 - 101,0                                 | 100,0   | % <i>m/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

15-03-13

Expiration: 10-2014

Conclusion: APPROVED

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