



Certificate of Analysis

Productname: Atropini sulfas
Number of analysis/Inspection Code: 1 / KEUR-111207B
Batchnumber: 14G04-B01-298431 ✓
Reference code / No.: 3273 / APS1402001
Analysed according to: PH.EUR 8.2

FARMADENT d.o.o.	
Minariškova ul. 6	
2000 Maribor	
Projek: FUJS DRAGO	
Datum pregleda:	5.5.2015
Pregledat: M. BOLT Robert, mag. farm., spec.	
Datum pregleda:	5.5.2015

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	4,9		2% <i>m</i> / <i>V</i>
Optical rotation	-0,50 - +0,05	-0,01	°	
Related substances	Conform	Conform		HPLC
Impurity E	<=0,3	<0,3	%	
Impurity H	<=0,3	<0,3	%	
Impurity A	<=0,2	0,10	%	
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,2	<0,2	%	
Impurity D	<=0,2	<0,2	%	
Impurity F	<=0,2	<0,05	%	
Impurity G	<=0,2	<0,2	%	
Unspecified impurities	<=0,10	<0,10	%	
Total impurities	<=0,5	<0,5	%	
Water (Karl Fischer)	2,0 - 4,0	3,4	%	
Sulphated ash	<= 0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Atropine sulphate	99,0 - 101,0	101,0	% <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 Eurofins Parijs.

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

08/25/14

Expiration: 02-2016

Conclusion: APPROVED