



Certificate of Analysis

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO
7A: H
Datum prejema: 8.4.14
Pregledal: MAROLT Robert, mag. farm. spec.
Datum pregleda: 8.4.2014

Productname: Atropini sulfas
Number of analysis/Inspection Code: 1 / KEUR-103150B
Batchnumber: 13K08-B06-288288
Reference code / No.: 3273 / APS1304001
Analysed according to: PH.EUR 7.8

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	5,2		2% <i>m</i> / <i>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	0,16	%	
Impurity B	<=0,2	n.d.	%	
Impurity C	<=0,2	0,08	%	
Impurity D	<=0,2	n.d.	%	
Impurity F	<=0,2	n.d.	%	
Impurity G	<=0,2	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,2	%	
Water (Karl Fischer)	2,0 - 4,0	3,1	%	
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</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

01/08/14

Expiration: 04-2015

Conclusion: APPROVED



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