



Certificate of Analysis

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGO
K.A. M.
Datum prejema: 9.5.13
Pregledal: MAROLT Robert, mag. farm., spec.
JA gmo
Datum pregleda: 13.5.2013

Productname: **Atropini sulfas**
Number of analysis/Inspection Code: 1 / KEUR-84876B
Batchnumber: **12F05-B06-272071** ✓
Reference code / No.: 3273 / APS1203006
Analysed according to: **PH.EUR 7.4**

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% m/V
Optical rotation	-0,50 - +0,05	0,00	°	10% m/V; 2 dm
Related substances	Conform	Conform		HPLC
Impurity E	<=0,3	n.d.	%	
Impurity H	<=0,3	n.d.	%	
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,2	n.d.	%	
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	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Water (Karl Fischer)	2,0 - 4,0	3,0	%	
Sulphated ash	<= 0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Atropine sulphate	99,0 - 101,0	99,6	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

19-06-12

Expiration: 03-2014

Conclusion: APPROVED

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