

## Certificate of Analysis

**Productname:** Atropini sulfas  
**Number of analysis/Inspection Code:** 1 / KEUR-180742B  
**Batchnumber:** 19L13-F01-368072  
**Reference code / No.:** 3273 / A-APS1908003  
**Analysed according to:** PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder or colorless crystals	Conform		
Identification A	-0,50 - +0,05	Conform	°	Optical rotation
Identification B	Conform	Conform		IR-spectrum
Identification E	Conform	Conform		Sulphate
pH	4,5 - 6,2	5,0		2%m/V
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	n.d.	%	
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	0,0	%	
Water (Karl Fischer)	2,0 - 4,0	2,8	%	
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Atropine sulphate	99,0 - 101,0	99,3	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:

dr. M.J. Vincenten - van Maanen

Pharmacist - Qualified Person

02/26/20

Expiration: 08-2022

Conclusion: APPROVED

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