

Geldig van 30 DEC 2021
tot 30 DEC 2024



QUALITY CONTROL DEPARTMENT

ATROPINI SULFAS
ANALYSIS REPORT: 22A17-APR22034

AUTHORISATION	1890R06131	DATE OF ANALYSIS	24/11/2021
LOT NUMBER	22A17-APR22034	EXPIRY DATE	03/2024
PRODUCTION NUMBER	270122-GS21112	ANALYTICAL REFERENCE	PH. EUR. 10.5 [04/2008:0068] CORR.10.0

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder or colourless crystals	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Optical rotation: - 0.50° to + 0.05°	+ 0.01
Identification B	The spectrum complies with the spectrum obtained with atropine sulfate CRS	Complies
Identification E	It gives the reactions of sulfates	Complies
TESTS	SPECIFICATION	RESULT
pH	4.5 to 6.2	5.0
Optical rotation	-0.50° to + 0.05°	+0.01
Related substances		
Impurity E	≤ 0.3%	Not detected
Impurity H	≤ 0.3%	Not detected
Impurity A	≤ 0.2%	Not detected
Impurity B	≤ 0.2%	Not detected
Impurity C	≤ 0.2%	Not detected
Impurity D	≤ 0.2%	Not detected
Impurity F	≤ 0.2%	Not detected
Impurity G	≤ 0.2%	Not detected
Unspecified impurities	≤ 0.10%	< 0.05 %
Total	≤ 0.5%	< 0.05 %
Water	2.0% to 4.0%	3.3 %
Sulfated ash	≤ 0.1%	0.04 %
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (anhydrous substance)	99.4 %

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:


Maxime Brits

DATE: 07/12/2022