

ATROPINI SULFAS 1 g

Lot No.: 24A15-APR24017

Autorisation :	1890R06131	Date Of Analysis :	03/11/2023
Analytical Reference :	Ph. Eur. 10.6 [04/2008 :0068] Corr. 10.0	Production Number :	230124-GS23106
CNK :	4490-058	Expiry Date :	12/2025

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°	-0.03°
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	4.7
Optical rotation	-0.50° to + 0.05°	-0.03°
Related substances		
Impurity E	≤ 0.3%	< 0.05%
Impurity H	≤ 0.3%	< 0.05%
Impurity A	≤ 0.2%	< 0.05%
Impurity B	≤ 0.2%	< 0.05%
Impurity C	≤ 0.2%	< 0.05%
Impurity D	≤ 0.2%	< 0.05%
Impurity F	≤ 0.2%	< 0.05%
Impurity G	≤ 0.2%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Water	2.0% to 4.0%	2.4%
Sulfated ash	≤ 0.1%	0.04%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (anhydrous substance)	100.1%
Manufacturer identification code: S/GS/163		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: