



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250042

Product:	ATROPINE SULPHATE
Lot:	250042
Expiry date:	30/08/2028
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	(C17H23NO3)2·H2SO4·H2O
Molecular weight:	694,84 g/mol

Assay	Result	Specification	
Identification	Conform (A,B,E)	Test PhEur (A,B,E)	
Organoleptic properties	Conform	PhEur	
pH aqueous solution 2%	5,5	4,5 - 6,2	
Optical rotation	-0,01°	(-0,5°)-(+0,05°)	
Related substances (HPLC)	Conform	Test PhEur	
Moisture - K.F. (s/0,5g)	3,1 %	2,0-4,0%	
Sulphated ashes	0,04 %	<= 0,1 %	
ASSAY (anhydrous vehicle PFP)	100,1 % s.p.s.	99,0 - 101,0% s.p.s.	
Impurity A	ND	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,2 %	
Impurity C	ND	<= 0,2 %	
Impurity D	ND	<= 0,2 %	
Impurity E	ND	<= 0,3 %	
Impurity F	ND	<= 0,2 %	
Impurity G	ND	<= 0,2 %	
Impurity H	ND	<= 0,3 %	
Unspecified Impurities	ND	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,5 %	
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Very soluble in water, freely soluble in ethanol 96%.

Conservation: In tightly closed containers. Protect form light and moisture.

Date of analysis: 29/01/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00384 SAURAV CHEMICALS LIMITED

Manufacturer batch: ATS240004

Product	Name	Capacity	Batch
1104283	ATROPINA SULFATO	5 g	250042-E-2
1370157	ATROPINA SULFATO (FLB)	5 g	250042-E-1
1370157	ATROPINA SULFATO (FLB)	5 g	250042-E-3

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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