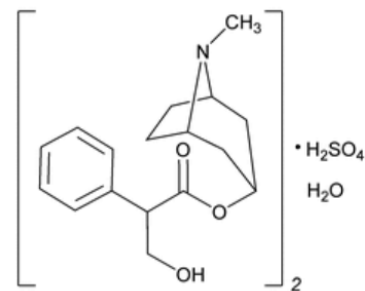


Atropine Sulfate USP

Atropine is a well-known tropane alkaloid muscarinic antagonist used to treat poisoning by certain nerve agents, including organophosphates and other drugs. This anticholinergic medication is also used to treat some heart rate conditions, and to decrease saliva production during surgery. It is typically given intravenously or by injection into a muscle. The alkaloid, originally from *Atropa belladonna*, but found in other plants of the Solanaceae family (*Duboisia*, *Datura* & *Hyoscyamus*).



Formula: $C_{17}H_{23}NO_3 \cdot H_2SO_4 \cdot H_2O$

Mol. weight: 676.82

Batch release specifications

Test	Specification	Method	
Description	White, crystalline powder, colourless	Current USP	
Identification A: I.R.	I.R. spectrum corresponds to reference spectrum	Current USP	
Identification B: Sulfate	Meets the requirements for sulfate	Current USP	
Identification C: RT	The retention time of the major peak of the sample solution corresponds to that of the system suitability solution, as obtained in the Assay	Current USP	
Assay	98% to 102.0%	Current USP	
Organic impurities	Tropic acid	NMT 0.2%	Current USP
	7-OH Hyoscyamine	NMT 0.2%	
	Scopolamine	NMT 0.2%	
	6-OH Hyoscyamine	NMT 0.2%	
	Norhyoscyamine	NMT 0.3%	
	Littorine	NMT 0.2%	
	Apoatropine	NMT 0.2%	
	Other impurities	NMT 0.1%	
Total impurities	NMT 0.5%		
Impurities: Residue on ignition	NMT 0.2%	Current USP	
Residual solvents	Chloroform < 60 ppm Acetone < 5000 pm	Current USP	
Specific optical rotation	-0.50° to +0.05°	Current USP	
Quantitate filter test (Phytex only)	NMT 0.1% residue No particles observed different to blank	SPEC.612 Phytex	

This product has been manufactured according to the ICH GMP Guide for APIs

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