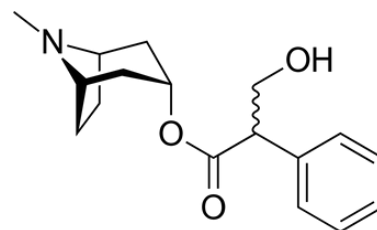


Atropine Base EP (European Pharmacopoeia)

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: $C_{17}H_{23}NO_3$

Mol. weight: 289.37

Batch release specifications

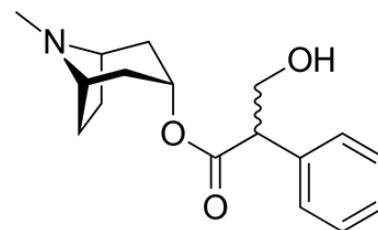
Test	Specification	Method																				
Description	White or almost white, crystalline powder or colourless crystals	Current EP																				
Identification A	Melting point: 115 °C to 119 °C	Current EP																				
Identification B	I.R. spectrum corresponds to reference spectrum	Current EP																				
Identification E	-0.70° to +0.05°	Current EP																				
Optical rotation	-0.70° to +0.05°	Current EP																				
Related substances (HPLC)	<table border="1"> <tbody> <tr> <td>A: Apoatropine</td> <td>NMT 0.2%</td> </tr> <tr> <td>B: Noratropine</td> <td>NMT 0.2%</td> </tr> <tr> <td>C: Tropic acid</td> <td>NMT 0.2%</td> </tr> <tr> <td>D: 6-hydroxyhyoscyamine</td> <td>NMT 0.2%</td> </tr> <tr> <td>E: 7-hydroxyhyoscyamine</td> <td>NMT 0.3%</td> </tr> <tr> <td>F: Hyoscine</td> <td>NMT 0.2%</td> </tr> <tr> <td>G: Littorine</td> <td>NMT 0.2%</td> </tr> <tr> <td>H: Unknown structure</td> <td>NMT 0.3%</td> </tr> <tr> <td>Other impurity</td> <td>NMT 0.10%</td> </tr> <tr> <td>Total</td> <td>NMT 0.5%</td> </tr> </tbody> </table>	A: Apoatropine	NMT 0.2%	B: Noratropine	NMT 0.2%	C: Tropic acid	NMT 0.2%	D: 6-hydroxyhyoscyamine	NMT 0.2%	E: 7-hydroxyhyoscyamine	NMT 0.3%	F: Hyoscine	NMT 0.2%	G: Littorine	NMT 0.2%	H: Unknown structure	NMT 0.3%	Other impurity	NMT 0.10%	Total	NMT 0.5%	Current EP
A: Apoatropine	NMT 0.2%																					
B: Noratropine	NMT 0.2%																					
C: Tropic acid	NMT 0.2%																					
D: 6-hydroxyhyoscyamine	NMT 0.2%																					
E: 7-hydroxyhyoscyamine	NMT 0.3%																					
F: Hyoscine	NMT 0.2%																					
G: Littorine	NMT 0.2%																					
H: Unknown structure	NMT 0.3%																					
Other impurity	NMT 0.10%																					
Total	NMT 0.5%																					
Loss on drying	NMT 0.2%	Current EP																				
Assay	99.0% - 101.0%	Current EP																				
Residual solvents	Chloroform < 60 ppm Acetone < 5000 ppm	Current EP																				

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

Phytex is a member company of the Active Pharmaceutical Ingredient Manufacturers Association of Australia and a current Silver Status provider of USP reference standard material distributed under the Donor Recognition Program.

Atropine Base USP (United States Pharmacopeia specification)

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: $C_{17}H_{23}NO_3$

Mol. weight: 289.37

Batch release specifications

Test	Specification	Method																		
Description	White, crystalline powder, colourless	Current USP																		
Identification A	The IR absorption spectrum, determined in a 1-mm cell of solution of the sample exhibits maxima only at the same wavelengths as that of the solution of the standard.	Current USP																		
Identification B	A lusterless precipitate is formed	Current USP																		
Assay	99.0% - 100.5%	Current USP																		
Organic impurities (HPLC)	<table border="1"> <tbody> <tr> <td>A: Apotropine</td> <td>NMT 0.2%</td> </tr> <tr> <td>B: Noratropine</td> <td>NMT 0.2%</td> </tr> <tr> <td>C: Tropic acid</td> <td>NMT 0.2%</td> </tr> <tr> <td>D: 6-hydroxyhyoscyamine</td> <td>NMT 0.2%</td> </tr> <tr> <td>E: 7-hydroxyhyoscyamine</td> <td>NMT 0.3%</td> </tr> <tr> <td>F: Hyoscyne</td> <td>NMT 0.2%</td> </tr> <tr> <td>G: Littorine</td> <td>NMT 0.2%</td> </tr> <tr> <td>Other impurity</td> <td>NMT 0.10%</td> </tr> <tr> <td>Total</td> <td>NMT 0.5%</td> </tr> </tbody> </table>	A: Apotropine	NMT 0.2%	B: Noratropine	NMT 0.2%	C: Tropic acid	NMT 0.2%	D: 6-hydroxyhyoscyamine	NMT 0.2%	E: 7-hydroxyhyoscyamine	NMT 0.3%	F: Hyoscyne	NMT 0.2%	G: Littorine	NMT 0.2%	Other impurity	NMT 0.10%	Total	NMT 0.5%	In-house quantitative HPLC validation
A: Apotropine	NMT 0.2%																			
B: Noratropine	NMT 0.2%																			
C: Tropic acid	NMT 0.2%																			
D: 6-hydroxyhyoscyamine	NMT 0.2%																			
E: 7-hydroxyhyoscyamine	NMT 0.3%																			
F: Hyoscyne	NMT 0.2%																			
G: Littorine	NMT 0.2%																			
Other impurity	NMT 0.10%																			
Total	NMT 0.5%																			
Impurities: Organic impurities (TLC)	Foreign alkaloids and other impurities	NMT 0.2%																		
Impurities: Residue on ignition	NMT 0.1%	Current USP																		
Residual solvents	Chloroform < 60 ppm Acetone < 5000 ppm	Current USP																		
Optical rotation	-0.70° to +0.05°	Current USP																		

Continues to page 2

Batch release specifications continued

Test	Specification	Method
Readily carbonisable substances test	Meets the requirements	Current USP
Water determination	NMT 0.2%	Current USP
Melting temperature	114°C to to 118°C	Current USP
Quantitate filter test (Phytex only)	NMT 0.1% residue No particles observed different to blank	SPEC .610 Phytex

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

Phytex is a member company of the Active Pharmaceutical Ingredient Manufacturers Association of Australia and a current Silver Status provider of USP reference standard material distributed under the Donor Recognition Program.