

### Scopolamine Butylbromide EP8

Criteria	Method	Unit	Typical
Characters	Visual	White or almost white crystalline powder, freely soluble in water and methylene chloride, sparingly soluble in ethanol	Complies
Infrared spectrum compare	EP 8th Edition 2.2.24	Compares to the spectrum of CRS	Complies
Reaction for bromides	EP 8th Edition 2.3.1	Positive reaction for bromides	Complies
Solution is clear	EP 8th Edition 2.2.1	Solution is clear	Complies
Solution colourless	EP 8th Edition 2.2.2 (II)	Solution is colourless	Complies
pH of Solution	EP 8th Edition 2.2.3	pH units	6.2
Optical Rotation	EP 8th Edition 2.2.7	Degrees of optical rotation	Neg 19.7
Hyoscine and related substances			
i. Impurity A peak	EP 8th Edition 2.2.29	area	< 0.1
ii. Impurities B, C, D, E, F & G peaks		area	< 0.2
iii. Any other impurity peak		area	< 0.1
iv. Total impurities peaks		area	< 0.4
Loss on Drying	EP 8th Edition 2.2.32	% m/m	0.14
Sulphated Ash	EP 8th Edition 2.4.14	% m/m	0.01
Assay - potentiometric	EP 8th Edition 2.2.20	% m/m	99.2
Residual Solvents:			
a. Methanol	EP 8th Edition 2.4.24	mg/kg	< 3000
b. Chloroform		mg/kg	nd