

Scopolamine Hydrobromide

Criteria	Method	Unit	Typical
Characters	Visual	White or almost white crystalline powder or colourless crystals, freely soluble in water and soluble in ethanol	Complies
B. Infrared spectrum compare	EP 8th Edition 2.2.24	Compares with the spectrum of CRS	Complies
Reaction for bromides	EP 8th Edition 2.3.1	Gives positive reaction for bromides	Complies
pH of Solution S	EP 8th Edition 2.2.3	pH units	4.35
Optical Rotation	EP 8th Edition 2.2.7	Degrees of optical rotation	Neg 25.4
Water	EP 8th Edition 2.5.12	% m/m	11.3
Sulphated Ash	EP 8th Edition 2.4.14	% m/m	0.02
Assay - potentiometric	EP 8th Edition 2.2.20	% m/m	98.9
Hyoscine and related substances			
i. Impurity B peak	EP 8th Edition 2.2.29	area	< 0.5
ii. Impurities A, C, D peaks	EP 8th Edition 2.2.29	area	< 0.1
iii. Any other impurity peak	EP 8th Edition 2.2.29	area	< 0.1
iv. Total impurities peaks	EP 8th Edition 2.2.29	area	< 0.7
Residual Solvents:			
Chloroform	EP 8th Edition 2.4.24	mg/kg	< 60