

Hyoscine Hydrobromide

(Typical Analysis)

Criteria	Specification	Typical Result
Characters	White or almost white crystalline powder or colourless crystals, efflorescent; Freely soluble in water and soluble in ethanol	Complies
Infrared absorption spectrophotometry	Compares with the spectrum obtained with Hyoscine Hydrobromide (CRS)	Complies
Reaction of Bromides	Gives positive reaction for bromides	Complies
pH of solution S	4.0 to 5.5	4.52
Specific optical rotation of Solution S	Negative 24° to Negative 27°	Negative 26.0
Hyoscine and other related substances (by HPLC)		
Impurity A: Hyoscyamine	NMT 0.1 %	Complies
Impurity B: Norhyoscine	NMT 0.5 %	Complies
Impurity C: Apohyoscine	NMT 0.1 %	Complies
Impurity D: Tropic Acid	NMT 0.1 %	Not Detected
Any other impurity	NMT 0.1 %	Not Detected
Total impurities	NMT 0.7 %	Complies
Water	10.0% to 13.0%	11.21
Sulphated Ash	NMT 0.1 %	0.01
Assay – potentiometric	99.0% to 101.0%	99.9
Residual Solvents		Complies

