

## Hyoscine Butylbromide

(Typical Analysis)

Criteria	Specification	Typical Result
Character	White or almost white crystalline powder, Freely soluble in water and methylene chloride, sparingly soluble in anhydrous ethanol	Complies
Infrared absorption spectrophotometry	Compares with the spectrum obtained with Hyoscine Butylbromide (CRS)	Complies
Reaction of Bromides	Gives positive reaction for bromides	Complies
Solution S is clear	Solution is clear	Complies
Solution S is colourless	Solution is colourless	Complies
Acidity or Alkalinity	NMT 0.5 mL of 0.01 M HCl	Complies
Specific optical rotation of Solution S	Negative 18° to Negative 20°	Negative 19.7
Hyoscine and other related substances		
Impurity A: Hyoscine	NMT 0.15 %	<0.05
Individual unspecified impurities	NMT 0.10 % NMT 0.4 %	<0.05 <0.1
Total impurities		
Other impurities n-Butylbromide	NMT 10 ppm	30
Loss on Drying	NMT 2.5 %	0.02
Sulphated Ash	NMT 0.1 %	<0.01
Assay – potentiometric	98.0% to 101.0%	99.1
Residual Solvents		Complies

