

## Hyoscyamine Sulphate USP40

Batch no

20240101

Mf date

Jan 05 2024

Retest

Jan 04 2027

 $\label{eq:molecular formula} \begin{array}{ll} \text{Molecular Formula} & \text{$C_{34}$H}_{48}\text{$N_2$O}_{10}\text{$S$} \cdot 2\text{$H_2$O} \end{array}$ 

Molecular Weight 713

CAS Registry Number 620-61-1

Apr 11 2024

Tests	Specifications		Results
Appearance	White or almost white crystalline powder		Almost white
***************************************	or colourless needles		crystalline powder
Identification	IR, RRT, reaction of sulphates		Positive
Melting range	187. 0 ~ 194. 0°C		188. 4 ~ 193. 6°C
Hq	4.5 ~ 6.2		5. 5
Specific optical rotation	−24 ~ −29°		-28. 5°
Water	2.0 ~ 5.5%		3. 2%
Residue on ignition	≤ 0.1%		0. 03%
Chromatographic purity	DL-Tropic acid	≤ 0.2%	< 0.05%
	7-Hydroxyhyoscyamine	≤ 0. 2%	< 0.05%
	6-Hydroxyhyoscyamine	≤ 0. 2%	< 0.05%
	Scopolamine	≤ 0. 2%	< 0.05%
	Norhyoscyamine	≤ 0.3%	< 0.05%
	Apoatropine	≤ 0. 2%	< 0.05%
	Littorine	<ul><li>≤ 0. 2%</li></ul>	< 0.05%
	Any other individual in		< 0.05%
	Total impurities	≤ 0.5%	< 0.05%
Residual solvents	Chloroform	< 60 ppm	0.00% 0 ppm
	Ethyl ether	< 5000 ppm	750 ppm
	Ethanol	< 5000 ppm	
Assay	98. 5 ~ 100. 5%	₹ 3000 ppili	580 ppm 99.1%
	100.0/0		99. 1%
Packaging & storage	Keep container tightly closed in a dry place		
Conclusion	Material complies with USP40		