



American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Spasmocan injection (Hyoscine Butylbromide Injection 20mg/ml)		
Batch No.	25AR045	A.R. No.	AFP250049
Batch Size	200000 Ampoule	Sample Quantity	60 Nos
Mfg. Date	10/2025	Date of Testing	07/11/2025
Exp. Date	09/2028	Date of Release	24/11/2025
Reference Batch No	25AR045	MFG. Lic. No.	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	A clear, colourless liquid.	Clear and colorless liquid.
2.	Identification	<p>A). By IR: Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with hyoscine Butylbromide IPRS or with the reference spectrum of hyoscine Butylbromide.</p> <p>B). By UV : When examined in the range 230 nm to 360 nm , 0.15 per cent w/v solution in 0.01 M hydrochloric acid shows absorption maxima at about 252 nm, 257 nm and 264 nm and a less well-defined maximum at about 247 nm.</p> <p>By Chemical: To 1 mg add 0.2 ml of fuming nitric acid and evaporate to dryness on a water-bath. Dissolve the residue in 2 ml of acetone and add 0.1 ml of a 3 per cent w/v solution of potassium hydroxide in methanol, a violet colour is produced.</p>	Complies
3.	pH	3.7 to 5.5	4.57
4.	Extractable Volume	NLT 1.0 ml	1.0 ml



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5.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
6.	Hyoscine	Determine by liquid chromatography	Complies
7.	Related substances	1) Hyoscine impurity G NMT1 % 2) Any other secondary peak is not more than 0.2 3) The sum of the areas of all the secondary peaks is not more than 2.5 %	Complies
8.	Bacterial Endotoxins	NMT 8.75 EU/mg	Complies
9.	Sterility	Should be Sterile	Sterile
10.	Assay: Each ml Contains Hyosciene Butylbromide IP 20mg	18.5 mg to 21.5 mg 92.5 % to 107.5%	20.22 mg 101.09 %

Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date			
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC