AMERICAN REMEDIES
Care & Cure with Research

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 IP 20mg/ml)**		
Batch No.	26AR110	**A.R. No.**	AFP260118
Batch Size	10400 Ampoule	**Sample Quantity**	60 Amps.
Mfg. Date	09/2026	**Date of Testing**	27/09/2026
Exp. Date	08/2028	**Date of Release**	14/10/2026
Reference Batch No	26AR110	**MFG. Lic. No.**	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	**Description**	A clear, colourless liquid filled in amber colour ampoule.	Clear and colorless liquid filled in amber colour ampoule.
2.	**Identification**	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.	Complies
		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.	Complies
		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.	Complies
3.	**pH**	3.7 to 5.5	4.80
4.	**Extractable Volume**	NLT 1.0 ml	1.0 ml
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

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	**Spasmocan Injection (Hyoscine Butylbromide Injection IP 20mg/ml)**		
Batch No.	26AR110	**A.R. No.**	AFP260118
Batch Size	10400 Ampoule	**Sample Quantity**	60 Amps.
Mfg. Date	09/2026	**Date of Testing**	27/09/2026
Exp. Date	08/2028	**Date of Release**	14/10/2026
Reference Batch No	26AR110	**MFG. Lic. No.**	HP-MB-LL-00235

6.	**Hyoscine**	Determine by liquid chromatography	Complies
7.	**Related substances** **Hyoscine impurity G** **Any other secondary peak** **Total Impurity**	 NMT 1.0 % NMT 0.2% NMT 2.5%	 Not Detected Not Detected Not Detected
8.	**Bacterial Endotoxins**	NMT 8.75 EU/mg	Less Than 8.75 EU/mg
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%	 20.29 mg 101.46 %

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

	Prepared By	**Checked By**	**Approved By**
Sign/Date	14/10/2026	14/10/2026	14/10/2026
Name	**Diksha Saini**	**Vinay Kumarr**	**Bhupinder Navet**
Designation	**Officer QC**	**Sr.Executive-QC**	**Head-QC**

AMERICAN REMEDIES HEALTHCARE PVT. LTD. QUALITY CONTROL MANAGER

Name: Bhupinder Navet
Designation: Head QC
Qualification: M. Pharma
Registration No: 12-DVI-103
Pt BD Sharma University of Health Sciences, Rohtak