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:	**NumbOn-B (Bupivacaine Injection IP 100mg/20ml)**		
Batch No.	26EAR004	**A.R. No.**	PV260710
Batch Size	21,000 Vials	**Sample Quantity**	40 Vials
Mfg. Date	08/2026	**Date of Testing**	31/08/2026
Exp. Date	07/2029	**Date of Release**	16/09/2026
Reference Batch No	NA	**MFG. Lic. No.**	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	**Description**	A clear colorless liquid solution in clear colourless vial	A clear colorless liquid solution in clear colourless vial
2.	**Identification** **A. By IR** **B. By Chemical**	Compare the spectrum with that obtained with bupivacaine hydrochloride Working Standard treated in the same manner. No pink color is produced.	Complies Complies
3.	**pH**	Between 4.0 to 6.5	5.05
4.	**Extractable Volume**	NLT 20.0 ml	20.0 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
6.	**Bacterial Endotoxins**	Not more than 2.5 EU/mg	Less than 2.5 EU/mg
7.	**Related substances (By TLC)**	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution.	Complies

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8.	**2.6-Dimethylaniline**	Any yellow colour produced is not more intense than the colour produced by preparation standard solution	Complies
9.	**Sterility**	Should be Sterile	Sterile
10.	**Assay:** **Each ml contains:** **Bupivacaine HCl IP 5 mg** **Sodium Chloride IP 8 mg** **Methyl Paraben IP 1 mg**	 (4.625 mg to 5.375 mg) 92.5% to 107.5% (7.20 mg to 8.80 mg) 90.0 % to 110.0 % (0.90 mg to 1.10 mg) 90.0 % to 110.0 %	 (5.106 mg) 102.13 % 8.26 mg 103.29 % (1.02 mg) 101.85 %

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

	Prepared By	Checked By	Approved By
Sign/Date	16/09/2026	16/09/2026	16/09/2026
Name	**Diksha Saini**	**Manisha Thakur**	**Bhupinder Navet**
Designation	**Officer QC**	**Executive QC**	**Head-QC**

AMERICAN REMEDIES HEALTHCARE PVT. LTD.
QUALITY CONTROL MANAGER