AMERICAN© REMEDIES	**American Remedies Healthcare Pvt. Ltd.** Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P) **QUALITY CONTROL DEPARTMENT**

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	**Sensorox 0.5 % (Bupivacaine Injection 100mg/20ml)**		
Batch No.	25AR055	**A.R. No.**	AFP250055
Batch Size	10100 Vials	**Sample Quantity**	60 Nos
Mfg. Date	10/2025	**Date of Testing**	14/11/2025
Exp. Date	09/2027	**Date of Release**	01/12/2025
Reference Batch No	25AR055	**MFG. Lic. No.**	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	**Description**	A clear colorless liquid solution	A clear colorless liquid solution
2.	**Identification** **A) (By IR)**	Compare the spectrum with that obtained with bupivacaine hydrochloride IPRS treated in the same manner or with the reference spectrum of bupivacaine.	Complies
	By chemical	To a volume containing 50 mg of anhydrous bupivacaine hydrochloride add 2 ml of a 10 per cent w/v solution of disodium hydrogen phosphate and sufficient iodine solution to produce a distinct brown colour. Remove the excess iodine by adding 0.1 M sodium thiosulphate; no pink colour is produced.	Complies
3.	**pH**	Between 4.0 to 6.5	6.59
4.	**Extractable Volume**	NLT 20.0ml	20.0ml
5.	**Bacterial Endotoxins**	Not more than 2.5 Endotoxin Units Per mg of bupivacaine hydrochloride.	NMT 2.5 Endotoxin Units per mg of bupivacaine hydrochloride.

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	Related substances **A) By TLC** **2.6-Dimethylaniline**	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. The yellow colour produced in test sample is not more intense than produced in standard solution.	Complies
6.	**Sterility**	Should be Sterile	Sterile
7.	**Assay:** **Each ml contains:** **Bupivacaine Hydrochloride IP 5mg**	(4.625 mg to 5.375 mg) 92.5% to 107.5%	4.962 mg 99.25 %

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

	Prepared By	**Checked By**	**Approved By**
Sign/Date	01/12/2025	01/12/2025	01/12/2025
Name	**Prayash**	**Manisha Thakur**	**Bhupinder Navet**
Designation	**Officer QC**	**Executive-QC**	**Head-QC**

AMERICAN REMEDIES (I) PVT. LTD. QUALITY CONTROL MANAGER