



American Remedies Healthcare Pvt. Ltd.

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

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Sensodex (Bupivacaine Injection 100mg/20ml)		
Batch No.	26AR059	A.R. No.	AFP260063
Batch Size	100450 Vials	Sample Quantity	60 Nos
Mfg. Date	05/2026	Date of Testing	19/05/2026
Exp. Date	04/2028	Date of Release	04/06/2026
Reference Batch No	26AR059	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	6.34
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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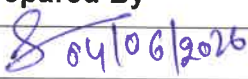
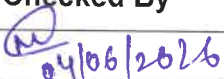
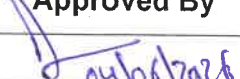
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	Related substances A) By TLC 2.6-Dimethylaniline	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution. The yellow colour produced in test 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%	5.03 mg 100.69 %

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

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

