

**CERTIFICATE OF FINISH PRODUCT ANALYSIS**

<b>Product Name:</b>	<b>Sensorox 0.5% Injection (Bupivacaine Injection 100mg/20ml)</b>		
<b>Batch No.</b>	25VF076B	<b>A.R. No.</b>	PV250680
<b>Batch Size</b>	10050 Vials	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	06/2025	<b>Date of Testing</b>	28/06/2025
<b>Exp. Date</b>	05/2027	<b>Date of Release</b>	15/07/2025
<b>Reference Batch No</b>	25VF076	<b>MFG. Lic. No.</b>	N-MB-2023/263

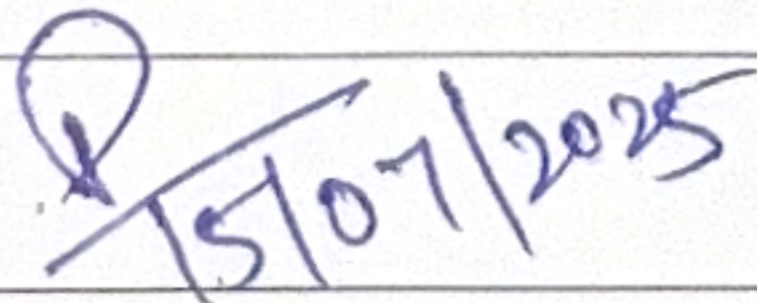
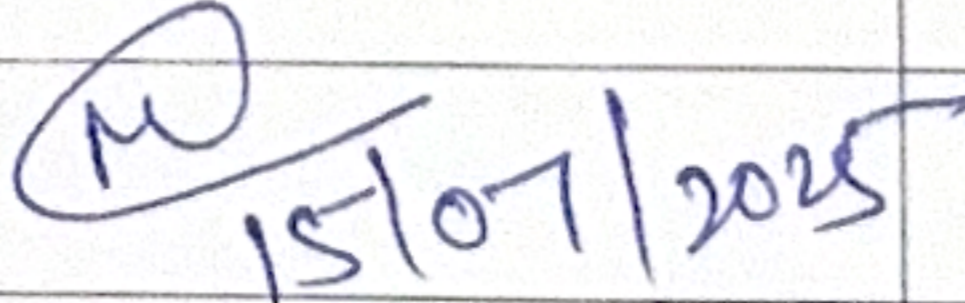
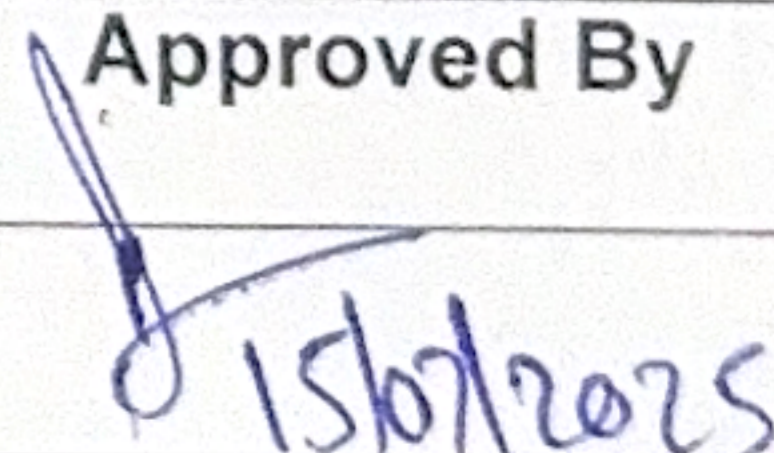
Sr. No.	Test	Specification	Observation
1.	<b>Description</b>	A clear colorless liquid solution	A clear colorless liquid solution
2.	<b>Identification</b> A) (By IR)	Compare the spectrum with that obtained with bupivacaine hydrochloride IPRS treated in the same manner or with the reference spectrum of bupivacaine.	Complies
	B) 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.	
3.	pH	Between 4.0 to 6.5	5.58
4.	<b>Extractable Volume</b>	NLT 20.0ml	20.0ml
5.	<b>Bacterial Endotoxins</b>	Not more than 2.5 Endotoxin Units Per mg of bupivacaine hydrochloride.	NMT 2.5 Endotoxin Units per mg of bupivacaine hydrochloride.
6.	<b>Related substances</b> A) 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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	<b>B) 2.6-Dimethylaniline</b>	The yellow colour produced in test sample is not more intense than produced in standard solution.	
<b>7.</b>	<b>Sterility</b>	Should be complies	Sterile
<b>8.</b>	<b>Assay:</b> Each ml contains: <b>Bupivacaine Hydrochloride IP</b> <b>5mg</b>	(4.625 mg to 5.375 mg) 92.5% to 107.5%	(5.015 mg) 100.31 %

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

	<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Sign/Date</b>	 15/07/2025	 15/07/2025	 15/07/2025
<b>Name</b>	Prayash	Manisha Thakur	Bhupinder Navet
<b>Designation</b>	Officer QC	Executive QC	Head-QC