



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

## Title : Certificate of Analysis Finished Product

Product Name	SENSODEX HEAVY Injection	A.R. No.	ARN/FP/25/087
Generic Name	Bupivacaine Hcl in Dextrose Injection USP 4ml	Sampled qty.	45 Ampoules
Batch No.	ARN25106A	Sampled by	Anuj Verma
Batch Size	99,750 Ampoules	Sampled on	23/01/2026
Mfg. Date	01/2026	Date of Testing	24/01/2026
Exp. Date	12/2027	Date of Release	07/02/2026

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear colour glass ampoule.	A clear colourless solution filled in clear colour glass ampoule.
2.	Identification (By TLC)  (By HPLC)	A. The R <sub>f</sub> value of the Bupivacaine spot obtained from the test preparation corresponds to those obtained from the adjacent chromatogram of standard preparation A and C. B. The retention time of the Bupivacaine peak in the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies  Complies
3.	Nominal fill volume	NLT 4ml	4.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	4.1 ml
5.	pH	4.0 to 6.5	6.02
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visible particulate matter	NMT 6000/Ampoule NMT 600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	4/Ampoule 1/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 1.8 USP EU/mg of Bupivacaine Hydrochloride.	Less than 1.8 USP EU/mg of Bupivacaine Hydrochloride.
9.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Bupivacaine Hydrochloride IP	5 mg	5.04091 mg	100.82%	93.0% to 107.0%
Dextrose Monohydrate IP	80 mg	83.37 mg	104.21%	93.0% to 107.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/HIS.

Analysis by  NAME: FIROJ KHAN	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI BHATNAGAR
---	---	---