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/25/038
Generic Name	Bupivacaine Hcl in Dextrose Injection USP 4ml	**Sampled qty.**	45 Ampoules
Batch No.	ARN2535A	**Sampled by**	Anuj Verma
Batch Size	1,00,000 Ampoules	**Sampled on**	16/10/2025
Mfg. Date	09/2025	**Date of Testing**	16/10/2025
Exp. Date	08/2027	**Date of Release**	31/10/2025

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)	**A.**The R_f value of the Bupivacaine spot obtained from the test preparation corresponds to those obtained from the adjacent chromatogram of standard preparation A and C.	Complies
	(By HPLC)	**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
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	4.96
6.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	(1.) Particles ≥10µm	NMT 6000/Ampoule	6/Ampoule
	(2.) Particles ≥25µm	NMT 600/ Ampoule	0/Ampoule
	(B.) Visible particulate matter	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	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	5.251 mg	105.02%	93.0% to 107.0%
Dextrose Monohydrate IP	80 mg	79.509 mg	99.39%	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/IHS.

Analysis by	Checked by	Approved by
31/10/25	31/10/25	31/10/25
NAME: RAMANJEET SINGH	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN