



QUALITY CONTROL DEPARTMENT

Certificate of Analysis of Finished Product

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/ FG/337/24-25

Report Date: 21-10-2024

Name of the product : SENSODEX HEAVY Injection 4ml
Generic Name : Bupivacaine Hydrochloride with Dextrose Injection USP
Batch No. : BD403
Batch Size : 52000
Mfg. Date. : OCT-2024
Exp. Date. : SEP-2026
Quantity of Sample : 50Nos
Date of Sampling : 06-10-2024
Date of Commencement of analysis : 06-10-2024
Date of Completion of analysis : 20-10-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description	A clear, colourless solution.	A clear, colourless solution
Identification A. By TLC: B. In the Assay	The Rf value of the Bupivacaine spot obtained from the test preparation corresponds to those obtained from the adjacent chromatograms of standard preparations A and C. The retention time of the Bupivacaine peak in the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies to USP specification Complies to USP specification
pH	4.0 to 6.5	5.91
Extractable Volume	NLT – 4.0ml/ Ampoule	4.1ml
Particulate matter	No visible particles	Complies
Bacterial Endotoxins	NMT 1.8EU/mg of Bupivacaine Hydrochloride	Less than 1.8EU/mg
Sterility Test	To comply as per IP	Complies
Assay : Each ml contains: Bupivacaine Hydrochloride I.P equivalent to anhydrous Bupivacaine Hydrochloride 5mg	(4.65 mg to 5.35mg) (93.0 to 107.0%)	5.22mg 104.40%
Dextrose monohydrate IP 80mg	74.4mg to 85.6mg 93.0% to 107.0%	81.00mg 101.25%

OBSERVATION: In the opinion of the undersigned the sample referred to above is of ~~Standard Quality~~ **Standard Quality** as in the act and the rules made there under for the reason given below.

REMARKS : COMPLIES AS PER USP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.

Analysed By:
Date: 21/10/2024

Checked By:
Date: 21/10/2024

Person In Charge of Testing
Date: 21/10/24

