



**Tamman Titoe Pharma Pvt Ltd**  
 56-57, Sidco Pharmaceutical Complex,  
 Alathur-603 110, Tamilnadu.

**QUALITY CONTROL DEPARTMENT**  
**Certificate of Analysis of Finished Product**  
 (Under Drug And Cosmetic Act. 1940 & The Rules There Under)

**Report No: TT/ FG/718/23-24**  
**Report Date: 29-03-2024**

Name of the product	: Sensodex Heavy Injection 4ml
Generic Name	: Bupivacaine Hydrochloride with Dextrose Injection USP
Batch No.	: BD401
Batch Size	: 52000
Mfg. Date.	: Mar-2024
Exp. Date.	: Feb-2026
Quantity of Sample	: 50Nos
Date of Sampling	: 14-03-2024
Date of Commencement of analysis	: 14-03-2024
Date of Completion of analysis	: 28-03-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description	A clear, colourless solution.	A clear, colourless solution
Identification	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.	Complies to USP specification
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.	Complies to USP specification
pH	4.0 to 6.5	6.01
Extractable Volume	NLT – 4.0ml/ Ampoule	4.1ml
Particulate matter	No visible particles	Complies
Bacterial Endotoxins	NMT 1.8EU/mg of Bupivacaine Hydrochloride	NLT 1.8 EU/mg
Sterility Test	To comply as per IP	Complies
Assay : Each ml contains:	(4.65 mg to 5.35mg)	5.19mg
Bupivacaine Hydrochloride I.P equivalent to anhydrous Bupivacaine Hydrochloride 5mg	(93.0 to 107.0%)	103.80%
Dextrose monohydrate IP 80mg	74.4mg to 85.6mg	78.76mg
	93.0% to 107.0%	98.45%

**OBSERVATION:** In the opinion of the undersigned the sample referred to above is of **Standard Quality** / ~~Not 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: 29/3/24

Checked By: V. [Signature]  
Date: 29.03.24

Person In Charge of Testing  
Date: [Signature]