# American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

**QUALITY CONTROL DEPARTMENT**

## CERTIFICATE OF FINISHED PRODUCT ANALYSIS

| | | | |
|---|---|---|---|
| **Product Name:** | **SENSOROX 0.5% Injection (Bupivacaine Hydrochloride Injection IP 100mg/20ml)** | | |
| **Batch No.** | 26AR090 | **A.R. No.** | AFP260112 |
| **Batch Size** | 20327 Vials | **Sample Quantity** | 60 Vials |
| **Mfg. Date** | 08/2026 | **Date of Testing** | 11/09/2026 |
| **Exp. Date** | 07/2028 | **Date of Release** | 28/09/2026 |
| **Reference Batch No** | 26AR090 | **MFG. Lic. No.** | HP-MB-LL-00235 |

| Sr. No. | Test | Specification | Observation |
|---|---|---|---|
| 1. | **Description** | A clear colorless liquid solution in clear colourless vial | A clear colorless liquid solution in clear colourless vial |
| 2. | **Identification**<br>**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 chemically** | 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. | Complies |
| 3. | **pH** | Between 4.0 to 6.5 | 6.25 |
| 4. | **Extractable Volume** | NLT 20.0 ml | 20.0 ml |
| 5. | **Particulate Matter** | Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye. | Complies |
| 6. | **Bacterial Endotoxins** | Not more than 2.5 EU/mg | Less than 2.5 EU/mg |

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| | | | |
|---|---|---|---|
| **7.** | **Related substances (By TLC)** | Complies | Complies |
| **8.** | **2.6-Dimethylaniline** | Yellow colour produced is not more intense than that obtained with a solution | Complies |
| **9.** | **Sterility** | Should be Sterile | Sterile |
| **10.** | **Assay:**<br>**Each ml contains:**<br>**Bupivacaine Hcl IP 5mg**<br><br>**Sodium Chloride IP 8 mg** | <br><br>4.625 mg to 5.375 mg<br>92.5% to 107.5%<br>7.20 mg to 8.80 mg<br>90.0 % to 110.0 % | <br><br>5.05 mg<br>100.95 %<br>8.14 mg<br>101.81 % |

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

| | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Sign/Date** | 28/09/2026 | 28/09/2026 | 28/09/2026 |
| **Name** | **Diksha Saini** | **Vinay Kumar** | **Bhupinder Navet** |
| **Designation** | **Officer QC** | **Sr.Executive QC** | **Head-QC** |

AMERICAN REMEDIES HEALTHCARE PVT. LTD. QUALITY CONTROL MANAGER

Name: Bhupinder Navet
Designation: Head QC
Qualification: M. Pharma
Registration No: 12-DVI-103
Pt BD Sharma University of Health Sciences, Rohtak