# American Remedies Healthcare Pvt. Ltd.

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

**QUALITY CONTROL DEPARTMENT**

## CERTIFICATE OF FINISHED PRODUCT ANALYSIS

| | | | |
|---|---|---|---|
| **Product Name:** | **Enoxacan Injection (Enoxaparin Sodium Injection IP 40 mg/0.4ml)** | | |
| **Batch No.** | 26AR119 | **A.R. No.** | AFP260123 |
| **Batch Size** | 5100 PFS | **Sample Quantity** | 60 PFS |
| **Mfg. Date** | 10/2026 | **Date of Testing** | 07/10/2026 |
| **Exp. Date** | 09/2028 | **Date of Release** | 22/10/2026 |
| **Reference Batch No** | 26AR119 | **MFG. Lic. No.** | HP-MB-LL-00235 |

| Sr. No. | Test | Specification | Observation |
|---|---|---|---|
| 1. | **Description** | Clear and colorless liquid filled in glass prefilled syringe. | Clear and colorless liquid filled in glass prefilled syringe. |
| 2. | **Identification** | | |
| | **A. By Chemical** | A creamy white precipitate should be formed. | Complies |
| | **B. By UV** | Show absorption maxima at 231 nm. | Complies |
| | **C. By Chemical** | Complies with the test for sodium | Complies |
| 3. | **pH** | 5.5 to 7.5 | 6.84 |
| 4. | **Benzyl Alcohol (if Present)** | 1.35 to 1.65% | Absent |
| 5. | **Free Sulphate** | NMT 0.12 % | Less Than 0.12% |
| 6. | **Extractable Volume** | NLT 0.4 ml | 0.4 ml |
| 7. | **Bacterial Endotoxins** | NMT 0.01 Endotoxin unit per unit of anti-factor $X_a$activityin Anti-factor $X_a$ IU. | Less than 0.01 Endotoxin unit per unit of anti-factor $X_a$activityin Anti-factor $X_a$ IU. |
| 8. | **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 |
| 9. | **Sterility** | Should be Sterile | Sterile |

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| | | | |
|---|---|---|---|
| 10. | **Assay: Each pre-filled syringe contains:**<br>**Enoxaparin Sodium IP**<br>**40 mg**<br>**(Equivalent to 4000 IU Anit-factor Xa units)** | **Anti factor $X_a$ activity**<br>3600 IU to 4400 IU<br>(90.0 to 110.0%)<br>**Anti factor $II_a$ activity**<br>NLT 2000 and NMT 3500 anti-factor $II_a$ IU per ml.<br>**Anti-factor $X_a$ to anti-factor $II_a$ ratio**<br>NLT 3.3 and NMT 5.3 | 4153.7 IU<br>(103.84%)<br><br>2609.75 IU per ml<br><br>3.98 % |

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

| | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Sign/Date** | 22/10/2026. | 22/10/2026 | 22/10/2026 |
| **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**