



## American Remedies Healthcare Pvt. Ltd.

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

### QUALITY CONTROL DEPARTMENT

#### CERTIFICATE OF FINISH PRODUCT ANALYSIS

<b>Product Name:</b>	<b>Enoxacan-80 Injection (Enoxaparin Sodium Injection IP 80 mg/0.8ml)</b>		
<b>Batch No.</b>	25AR076	<b>A.R. No.</b>	AFP250071
<b>Batch Size</b>	5100 PFS	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	12/2025	<b>Date of Testing</b>	16/12/2025
<b>Exp. Date</b>	11/2027	<b>Date of Release</b>	02/01/2026
<b>Reference Batch No</b>	25AR076	<b>MFG. Lic. No.</b>	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	<b>Description</b>	Clear and colorless liquid.	Clear and colorless liquid.
2.	<b>Identification</b>		
	<b>A. By Chemical</b>	A creamy white precipitate is formed.	Complies
	<b>B. By UV</b>	Show absorption maxima at 231 nm.	Complies
	<b>C. By Chemical</b>	Complies with the test for sodium	Complies
3.	<b>pH</b>	Between 5.5 to 7.5.	6.45
4.	<b>Benzyl Alcohol</b>	1.35 % to 1.65%	Absent
5.	<b>Free Sulphate</b>	NMT 0.12 %	Less Than 0.12%
6.	<b>Extractable Volume</b>	NLT 0.8 ml	0.8 ml
7.	<b>Bacterial Endotoxins</b>	NMT 0.01 Endotoxin unit per unit of anti-factor X <sub>a</sub> activity in Anti-factor X <sub>a</sub> IU.	Less than 0.01 Endotoxin unit per unit of anti-factor X <sub>a</sub> activity in Anti-factor X <sub>a</sub> IU.
8.	<b>Particulate Matter</b>	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.	<b>Sterility</b>	Should be Sterile	Sterile
10.	<b>Assay: Each pre-filled syringe contains:</b>	<b>Anti factor X<sub>a</sub> activity</b> NLT 90.00% to NMT 110.00%	101.66 %



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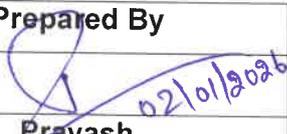
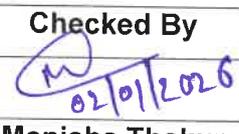
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Enoxaparin Sodium IP 80 mg (Equivalent to 8000 IU Anti-factor Xa units)	7200 IU to 8800 IU	8133.00 IU Anti-Factor Xa Units
	<b>Anti factor II<sub>a</sub> activity</b> NLT 2000 and NMT 3500 anti-factor II <sub>a</sub> IU per ml. <b>Anti-factor X<sub>a</sub> to anti-factor II<sub>a</sub> ratio</b> NLT 3.3 and NMT 5.3	2628.00 IU per ml  3.86

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

	<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Sign/Date</b>	 02/01/2026	 02/01/2026	 02/01/2026
<b>Name</b>	Prayash	Manisha Thakur	Bhupinder Navet
<b>Designation</b>	Officer QC	Executive-QC	Head-QC