



# American Remedies Healthcare Pvt. Ltd.

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

## CERTIFICATE OF FINISHED PRODUCT ANALYSIS

<b>Product Name:</b>	Enoxacan-40 Injection (Enoxaparin Sodium Injection IP 40 mg/0.4ml)		
<b>Batch No.</b>	26AR035	<b>A.R. No.</b>	AFP260038
<b>Batch Size</b>	24900 PFS	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	03/2026	<b>Date of Testing</b>	13/03/2026
<b>Exp. Date</b>	02/2028	<b>Date of Release</b>	28/03/2026
<b>Reference Batch No</b>	26AR035	<b>MFG. Lic. No.</b>	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid.	Clear and colorless liquid.
2.	Identification		
	A. By Chemical	A creamy white precipitate is formed.	Complies
	B. By UV	Show absorption maxima at 231 nm.	Complies
	C. By Chemical	Complies with the test for sodium	Complies
3.	pH	Between 5.5 to 7.5.	7.26
4.	Benzyl Alcohol	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 <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.	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
10.	Assay: Each pre-filled syringe contains:	<b>Anti factor X<sub>a</sub> activity</b> NLT 90.00% to NMT 110.00%	101.62 %



# 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-40 Injection (Enoxaparin Sodium Injection IP 40 mg/0.4ml)		
Batch No.	26AR035	A.R. No.	AFP260038
Batch Size	24900 PFS	Sample Quantity	60 Nos
Mfg. Date	03/2026	Date of Testing	13/03/2026
Exp. Date	02/2028	Date of Release	28/03/2026
Reference Batch No	26AR035	MFG. Lic. No.	HP-MB-LL-00235

Enoxaparin Sodium IP 40 mg (Equivalent to 4000 IU Anit- factor Xa units)	3600 IU to 4400 IU	4065.1 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></b> <b>ratio</b> NLT 3.3 and NMT 5.3	2601.34 IU per ml  3.90 %

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

	Prepared By	Checked By	Approved By
Sign/Date	 28/03/2026	 28/03/2026	 28/03/2026
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

