

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	ENOXACAN 40 (Enoxaparin Sodium Injection IP 40 mg/0.4ml)		
Batch No.	24PJ024A	A.R. No.	FP240081
Batch Size	14000 Nos	Sample Quantity	50 Nos
Mfg. Date	10/2024	Date of Testing	22/10 /2024
Exp. Date	09/2026	Date of Release	06/11/2024
Reference Batch No	24PJ024	MFG. Lic. No.	N-MB-2023/263

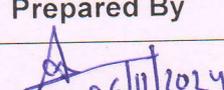
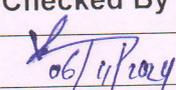
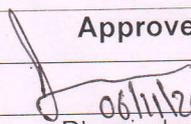
Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid.	Clear and colorless liquid.
2.	Identification		
	A. By Chemical	A creamy white precipitate is formed.	Complies
	B. By UV	Show absorption maxima at 231 nm.	Complies
	C. By Chemical	Complies with the test for sodium	Complies
3.	pH	Between 5.5 to 7.5.	6.48
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 _a activity in Anti-factor X _a IU.	Less than 0.01 Endotoxin unit per unit of anti-factor X _a activity in 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 complies	Sterile
10.	Assay: Each pre-filled syringe contains: Enoxaparin Sodium IP 40 mg	Anti factor X_a activity NLT 90.00% to NMT 110.00% 3600 IU to 4400 IU	102.01 % 4080.2 IU Anti-Factor X _a Units

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(Equivalent to 4000 IU Anit-factor X _a units)	Anti factor II_a activity NLT 2000 and NMT 3500 anti-factor II _a IU per ml.	2499.65 IU per ml
	Anti-factor X_a to anti-factor II_a ratio NLT 3.3 and NMT 5.3	4.08

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

	Prepared By	Checked By	Approved By
Sign/Date	 06/11/2024	 06/11/2024	 06/11/2024
Name	Abhay Mishra	Vikram Jeet	Bhupinder Navet
Designation	Sr. officer QC	Executive-QC	Head-QC