



Certificate of Analysis

ENOXAPARIN SODIUM INJECTION IP 60mg/0.6ml

BATCH No. : ENS324006E	ANALYTICAL REPORT No. FPPE/240034	MFG. DATE : MAY 2024
BRAND NAME : Enoxacan 60		EXP. DATE : APR. 2026
BATCH QUANTITY : 5000 PFS		PACKING DETAILS : 1 ML GLASS PRE FILLED SYRINGE PACKED IN SINGLE BLISTER ALONG WITH LEAFLET IN A MONOCARTON

S.No.	TESTS	RESULT	SPECIFICATION
1	Description	Clear Colorless solution prefilled syringe in blister pack.	Clear Colorless solution prefilled syringe in blister pack.
2	Identification By Chemical	A white precipitate formed	A creamy white precipitate is formed.
	By Ultraviolet Absorption	Complies	Spectra exhibit maxima at 231 ±2 nm.
	Sodium Test	Complies	Complies with the test for sodium.
3	Assay (Anti-Factor X _a Activity) (on dried basis)	102.2%	The potency is Not less than 90.0% and Not more than 110.0%. Of the potency stated on the label in terms of international Anti-Factor X _a units (IU).
4	Anti-factor X _a Activity to Anti-factor II _a activity ratio.	3.9	Not less than 3.3 and Not more than 5.3.
5	pH	6.5	Between 5.5- 7.5.
6	Bacterial Endotoxins	No gel formation	Not more than 0.01 Endotoxin Unit/IU of Anti factor X _a activity of Enoxaparin Sodium.
7	Anti -factor II _a activity	25.8%	Not less than 20.0 %and Not more than 35.0 % of the potency stated on

PREPARED BY	CHECKED BY	APPROVED BY
 06/07/2024	 06/07/2024	 06/07/2024
T. Officer -QC Aditya Sharma	Executive -QC Manish Batham	GM-Quality Ram Dular Yadav

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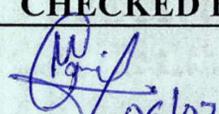
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			the label in terms of international Anti-factor X _a units (IU or IU/mL)
8	Free Sulfate	0.09%	Not more than 0.12%.
9	Sterility	Complies	Injections comply with the test for sterility.
10	Particulate matter in Injection	Complies	The clear colorless solution free from any particulate matter by visual appearance.
11	Extractable volume	Each PFS have volume not less than 0.6 mL	Not less than 0.6 mL per prefilled syringe.

THIS PRODUCT CONFORMS TO THE IP SPECIFICATIONS.

This COA issued for M/s American Remedies Healthcare Pvt Ltd

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