Deft Organics Limited

Reg. Office:
17 - Shree Ram Colony
Gwalior, (MP) - 474009

CIN: U24230MP1997PLC011987

Certificate of Analysis

ENOXAPARIN SODIUM INJECTION IP 40mg/0.4ml

BATCH No. : ENS224006B	ANALYTICAL REPORT No.	MFG. DATE : MAY 2024	
BRAND NAME : Enoxacan 40		EXP. DATE : APR. 2026	
BATCH QUANTITY : 5000 PFS	FPPE/240035	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 By Ultraviolet Absorption Sodium Test	A white precipitate formed Complies Complies	A creamy white precipitate is formed. Spectra exhibit maxima at 231 ±2 nm. Complies with the test for sodium.
3	Assay (Anti-Factor X_a Activity) (on dried basis)	102.9 %	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.	4.0	Not less than 3.3 and Not more than 5.3.
5	pH	6.6	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

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

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S.No.	TESTS	RESULT	SPECIFICATION
			Enoxaparin Sodium.
7	Anti –factor II_a activity	26.0%	Not less than 20.0 %and Not more than 35.0 % of the potency stated on 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 0.4 mL	Not less than 0.4 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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