

Title

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Certificate of Analysis Finished Product

Product Name	ENOXACAN 40 Injection	A.R. No.	NL/FP/23/635
Generic Name	Enoxaparin Sodium Injection IP 40mg/0.4ml	Sampled qty.	45 Pre-Filled Syringe
Batch No.	P23043D	Sampled by	Arvind
Batch Size	5000 Pre-filled Syringe	Sampled on	06/01/2024
Mfg. Date	12/2023	Date of Testing	06/01/2024
Exp. Date	11/2025	Date of Release	21/01/2024




S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in Pre-filled syringe.	A clear colourless solution filled in Pre-filled syringe.
2.	Identification	<p>A. Add 2 ml of water to the total content of a single-dose container or to 0.4 ml from a multiple-dose container, and 1 ml of 2 % w/v solution of protamine sulphate in a glass test tube. And mix. A creamy white precipitate is formed.</p> <p>B. Transfer the total content of a single dose container, or 0.4 ml from a multiple dose container; dilute to 100 ml with 0.01 M Hydrochloride acid. A 0.05 % w/v of reference solution shows absorption maxima at 231 nm.</p> <p>C. Complies with the test for sodium.</p>	<p>Complies</p> <p>Complies</p> <p>Complies</p>
3.	Nominal fill volume	NLT- 0.4 ml	0.4 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	0.4 ml
5.	pH	5.5 to 7.5	6.07
6.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/ Pre-Filled syringe NMT-600/ Pre-Filled syringe The solution is free from particles of foreign matter particles that can be observed on visual inspection.	45/Pre-Filled syringe 0/Pre-Filled syringe Complies
7.	Sterility	Liquid Injection should comply the test for sterility.	Complies
8.	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.

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9.	Composition: Each Pre-Filled syringe contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Enoxaparin Sodium I.P (Eq. to 4000 IU Anti factor Xa Units)		40 mg	38.922 mg	97.31%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/IHS.

Analysis by  Checked by  Approved by 
Manager

