

Pace

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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

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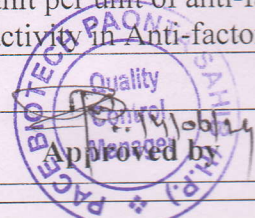
Certificate of Analysis Finished Product

Product Name	ENOXACAN 40 Injection	A.R. No.	NL/FP/24/128
Generic Name	Enoxaparin Sodium Injection IP 40mg/0.4ml	Sampled qty.	45 Pre-Filled Syringe
Batch No.	P24009A	Sampled by	Aakashdeep
Batch Size	7000 Pre-filled syringe	Sampled on	30/05/2024
Mfg. Date	05/2024	Date of Testing	30/05/2024
Exp. Date	04/2026	Date of Release	14/06/2024

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	5.86
6.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT-6000/ Pre-Filled syringe NMT-600/ Pre-Filled syringe	84/Pre-Filled syringe 0/Pre-Filled syringe
	(b.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	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.

Analysis by

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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	39.7547 mg	99.39%	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/HS.

Analysis by



Checked by



Approved by

