

# Pace

Add Pace To Health

# Pace Biotech

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

## Certificate of Analysis Finished Product

<b>Title</b>	:		
<b>Product Name</b>	ENOXACAN 60 Injection	<b>A.R. No.</b>	NL/FP/23/636
<b>Generic Name</b>	Enoxaparin Sodium Injection IP 60mg/0.6ml	<b>Sampled qty.</b>	45 Pre-Filled Syringe
<b>Batch No.</b>	P23042D	<b>Sampled by</b>	Arvind
<b>Batch Size</b>	5000 Pre-filled syringe	<b>Sampled on</b>	06/01/2024
<b>Mfg. Date</b>	12/2023	<b>Date of Testing</b>	06/01/2024
<b>Exp. Date</b>	11/2025	<b>Date of Release</b>	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><b>A.</b> 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>B.</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><b>C.</b> Complies with the test for sodium.</p>	Complies  Complies  Complies
3.	Nominal fill volume	NLT-0.6 ml	0.6 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	0.6 ml
5.	pH	5.5 to 7.5	6.29
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.	48/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 6000 IU Anti factor Xa Units )		60 mg	57.621 mg	96.04%	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
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