



HEILSA LIFE SCIENCES PVT. LTD.
 KII No. 940, 941, 942, Vill. - Kishanpur, Jamalpur, Bhagwanpur,
 Roorkee-247668. Distt. - Haridwar, (Uttarakhand) INDIA.

Quality control Department
Certificate of analysis Finished Product

Page 1 of 2

A.R. No: - ILS/FP/26/CG08

NAME OF PRODUCT	Enoxaparin Sodium Injection IP 40mg/0.4 ml		
BATCH NO.	PCG08	SAMPLED ON	30/07/2026
MFG. DATE	07/2026	QTY. SAMPLED	200 Nos.
EXP. DATE	06/2028	TESTED BY	Haripriya
BATCH SIZE	10 LTR	TESTING ON	31/07/2026
REFERENCE	As per IP	COMPLETION ON	17/08/2026

S. No.	Test	Specification	Observation
1.	Description	A clear colourless solution	A clear colourless solution.
2.	Identification A By Chemical: B. By UV: C. Test for Sodium:	A curdy white precipitate is formed Maxima at 231 nm A dense white precipitate is formed	A curdy white precipitate is formed Complies A dense white precipitate is formed
3.	pH	5.50 to 7.50	6.907
4*	Free sulphate	Not more than 0.12 percent	Not detected
5.	Bacterial Endotoxins	Not more than 0.01 Endotoxin Units per unit of anti-factor X _a activity in anti-factor X _a IU	Less than 0.01 Endotoxin Units per unit.
6.	Particulate Matter Visible Particles Subvisible Particles a) $\geq 10\mu\text{m}$ b) $\geq 25\mu\text{m}$	Should be absent Not more than 6000 Particles/container Not more than 600 Particles/container	Absent 9.628 Particles/container 0.08 Particles/container
7.	Extractable volume	Not less than 0.4 ml	0.4 ml
8.	Assay: anti-factor X _a activity Anti-factor II _a activity Anti-factor X _a to anti-factor II _a ratio.	NLT90.0 % to NMT110.0 % NLT 2000 to NMT 3500 anti-Factor II _a IU/ml NLT 3.3 to NMT 5.3	107.68 % 3106.09 IU/ml 3.60

	Prepared By	Reviewed By	Approved By
Name	Binay Bali Gupta	Kamal Kishor	Binay Bishwal
Designation	Jr. Officer - QC	QC- Executive	QC Head
Sign.			
Date	17/08/26	17/08/26	17/08/26

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Page 2 of 2

A.R. No: - HLS/FP/26/CG08

NAME OF PRODUCT	Enoxaparin Sodium Injection IP 40mg/0.4 ml		
BATCH NO.	PCG08	SAMPLED ON	30/07/2026
MFG. DATE	07/2026	QTY. SAMPLED	200 Nos.
EXP. DATE	06/2028	TESTED BY	Haripriya
BATCH SIZE	10 LTR	TESTING ON	31/07/2026
REFERENCE	As per IP	COMPLETION ON	17/08/2026

9.	Sterility	Complies with the test for sterility	Complies
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*This test is analysed by Idma laboratories Ltd.

Conclusion: The sample Complies / doesn't comply as per prescribed standards of IP and specification No: HLS/FPS/003.

	Prepared By	Reviewed By	Approved By
Name	Baijragbali Gupta	Kamal Kishor	Ramay Misra
Designation	Jr. Officer QC	QC - Executive	CQC Head
Sign.			
Date	17/08/26	17/08/26	17/08/26

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