



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

Quality control Department
Certificate of analysis Finished Product

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A.R. No: - HLS/FP/26/CG07

NAME OF PRODUCT	Enoxaparin Sodium Injection IP 60mg/0.6 ml		
BATCH NO.	PCG07	SAMPLED ON	30/07/2026
MFG. DATE	07/2026	QTY. SAMPLED	145 Nos.
EXP. DATE	06/2028	TESTED BY	Haripriya
BATCH SIZE	20 LTR	TESTING ON	30/07/2026
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	6.975
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 9.96 Particles/container 0.00 Particles/container
7.	Extractable volume	Not less than 0.6 ml	0.6 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 per ml NLT 3.3 to NMT 5.3	102.52 % 3050.17 IU/ml 3.49

	Prepared By	Reviewed By	Approved By
Name	Bayragbali Gupta	Kamal Kishor	Arjun C. Dewan
Designation	Jr. Officer-QC	QC- Executive	Manager QC
Sign.			
Date	17/08/26	17/08/26	17/08/26

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9.	Sterility	Complies with the test for sterility	Complies

*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/004.

	Prepared By	Reviewed By	Approved By
Name	Banjraybali gupth	Kamal Kishor	Arjun C. Newari
Designation	Jr officer-QC	QC- Executive	Manager
Sign.			
Date	13/08/26	17/08/26	17/08/26

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