



DERREN HEALTHCARE PRIVATE LIMITED

PLOT NO 33,35/P & 36/P, XCELON INDUSTRIAL PARK,
SARKHEJ-BAVLA HIGHWAY, VILL. VASNA - CHACHARWADI, -
TA : SANAND. DIST.AHMEDABAD - 382213, GUJARAT,INDIA

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FINISHED PRODUCT ANALYTICAL TEST REPORT

Product Name	PACEMOLOL INJECTION	Specification No.	DHPL/FP/SPEC/ESMOL/01/00
Generic Name	Esmolol Hydrochloride Injection IP 100 mg/10ml	Batch No. /Lot No.	DA25001
Each ml contains: Esmolol Hydrochloride10 mg Water for injection.....Q.S.		Mfg. Dt.	07/2025
		Exp. Dt.	06/2027
		Receipt Dt.	14/07/2025
		Release Dt.	28/07/2025
		Sample Size	41.000 Vial
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0174
Analysis	VIBHA KAMLESHBHAI PATEL	Manufactured By	DERREN
		Theoretical Yield/Batch Size	11,429.000 Vial

Sr.	Test	Limit	Result
1	Description	Clear, Colourless solution free from visible particles and fibres.	Clear, Colourless solution free from visible particles and fibres.
2	Extractable volume	NLT 10.0 ml	10.5 ml
3	IDENTIFICATION BY HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay
4	pH	4.5 to 5.5	4.8
5	Bacterial endotoxins	NMT 3.5 EU/ml of Esmolol Hydrochloride	Less than 3.5 EU/ml of Esmolol Hydrochloride
6	Particulate matter By Visual inspection By light obscuration method	The solution should be free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=NMT 6000/Container > 25 Microns=NMT 600/Container	The solution is free from particles that can be observed by inspection with the unaided eye. Sub visible particle by LPC >10 microns=6.00/Container > 25 Microns=0.00/Container
7	Sterility test	Should be sterile	sterile
8	Assay	90.0 to 110.0%% of the stated amount of Esmolol Hydrochloride	99.2%% of the stated amount of Esmolol Hydrochloride

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By 28/07/25	Checked By 28/07/25	Approved By 28/07/2025
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VIBHAP 28/07/2025 11:55 AM

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