

**DERREN HEALTHCARE PVT. LTD.**

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,
Ahmedabad-382 213, Gujarat (India)

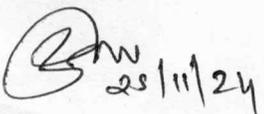
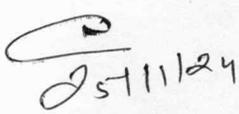
**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Name of Product	Esmolol Hydrochloride Injection IP 10 mg/ml(PACEMOLOL)		
Batch No.	DA24001	A.R. No.	FP/24/0128
Mfg. Date	11/24	Exp. Date	10/26
Sampled Qty.	41 Nos.	Date of Analysis	10/11/24
Batch Size	95 Ltr.	Date of Release	25/11/24
Container Type	Clear Glass Vial	Fill volume	10.0ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, Colourless solution free from visible particles and fibers.	Clear, Colourless or pale yellow solution free from visible particles and fibers.
2	Extractable volume	10.5 ml	NLT 10.0 ml
3	Identification		
3.1	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	4.97	4.5 to 5.5
5	Bacterial endotoxin	Less than 3.5 EU/ml Esmolol Hydrochloride	NMT 3.5 EU/ml of Esmolol Hydrochloride
6	Particulate matter		
6.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
6.2	By Light Obscuration Method	≥10 microns= 50.00 /Container ≥ 25 Microns= 7.33/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Each ml contains Esmolol Hydrochloride	101.2 %	90.0 to 110.0%% of the stated amount of Esmolol Hydrochloride

Conclusion: The above sample complies as per IP specification.

In the opinion of the undersigned the sample referred to above is **of standard / not of standard** quality as defined in the act and the rules made there under for the reasons given above.

Prepared By	Checked By	Approved By
 25/11/24 QC OFFICER	 25/11/24 QC EXECUTIVE	 25/11/24 QA MANAGER 