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	Labetalol Injection IP 5mg/ml		
Batch No.	AY23003	**A.R. No.**	FP/23/0083
Mfg. Date	12/23	**Exp. Date**	11/25
Sampled Qty.	41 Nos.	**Date of Analysis**	27/12/23
Batch Size	140 Ltr.	**Date of Release**	07/01/24
Container Type	Amber Glass Ampoules	**Fill volume**	5.0 ml
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	5.1 ml	NLT 5.0 ml
3	**Identification**		
3.1	Identification A by IR	The infrared absorption spectrum of the test preparation is concordant with the reference spectrum of the Labetalol hydrochloride WS.	The infrared absorption spectrum of the test preparation should be concordant with the reference spectrum of the Labetalol hydrochloride WS/RS.
3.2	Identification B by HPLC	In the Assay, the principal peak in the chromatogram obtained with test solution is correspond to the peak in the chromatogram obtained with reference solution (a).	In the Assay, the principal peak in the chromatogram obtained with test solution should be correspond to the peak in the chromatogram obtained with reference solution (a).
4	pH	4.0	3.5 to 4.5
5	Free carboxylic acid and other related substances	(1). The area of any spot corresponding to 5-[l-hydroxy-2- (l-methyl-3-phenylpropylamino) ethyl]salicylic acid is not more intense that the spot in the chromatogram obtained with reference solution (b). (2). The area of any other secondary peak is not more intense than the spot in the chromatogram, obtained with reference solution (a).	(1). The area of any spot corresponding to 5-[l-hydroxy-2- (l-methyl-3-phenylpropylamino) ethyl]salicylic acid should not more intense that the spot in the chromatogram obtained with reference solution (b). (2). The area of any other secondary peak should not more intense than the spot in the chromatogram, obtained with reference solution (a).
6	Bacterial endotoxin	Less than 1.2 EU/mg	NMT 1.2 EU/mg
7	**Particulate matter**		
7.1	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.
7.2	By Light Obscuration Method	≥10 microns= 25.67/Container ≥ 25 Microns= 0.00/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
8	Sterility test	Sterile	Should be sterile
9	**Assay**		
9.1	Each ml contains Labetalol hydrochloride IP 5.0 mg	98.4 %	90.0% to 115.0% of the stated amount of Labetalol hydrochloride

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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
07/01/24 QC OFFICER	07/01/24 QC EXECUTIVE	07/01/24 QA MANAGER