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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title	:	Certificate of Analysis Finished Product

Product Name	**METOFOX** Injection	**A.R. No.**	NL/FP/25/203
Generic Name	Metoprolol Tartrate Injection IP 5ml	**Sampled qty.**	45 ampoules
Batch No.	A25180A	**Sampled by**	Anuj
Batch Size	25,000 Ampoules	**Sampled on**	29/09/2025
Mfg. Date	08/2025	**Date of Testing**	29/09/2025
Exp. Date	07/2027	**Date of Release**	14/10/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.
2.	Identification (By IR)	**A.** Determine by infrared absorption spectrophotometry. Compare the spectrum with that obtained with metoprolol tartrate IPRS, treated in the same manner or with the reference spectrum of metoprolol.	Complies
	(By HPLC)	**B.** In the test for Related substances, the principal peak in the chromatogram obtained with reference solution (a) corresponds to the peak in the chromatogram obtained with reference solution (b).	Complies
	(By HPLC)	**C.** In the Assay, the principal peaks in the chromatogram obtained with the test solution corresponds to the principal peaks in the chromatogram obtained with reference solution.	Complies
3.	Nominal fill volume	NLT 5ml	5.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	5.1 ml
5.	pH	5.5 to 7.5	6.97
6.	Related substances (By HPLC)		
	Area of any secondary peak	NMT 0.3%	Not detected
	Total impurities	NMT 0.5%	Not detected

Analysis by	Checked by	Approved by
14/10/25	14/10/25	
NAME: RAMANJEET SINGH	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 580409039593
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Format No: PB/QC/045/F05-00

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7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm (B.) Visual Particle	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	3/Ampoule 0/Ampoule Complies
8.	Bacterial Endotoxins Test	NMT 25.0EU/mg of metoprolol tartrate.	Less than 25.0EU/mg of metoprolol tartrate.
9.	Sterility	No microbial growth should be observed.	Complies
10.	Assay: (By HPLC) Each ml contains		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Metoprolol Tartrate IP	1 mg	1.0488 mg	104.88%	95.0 to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not~~ complies as per IP/~~BP/USP/IHS.~~

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. 9041803959
Punjab Technical University Jalandhar
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NAME: RAMANJEET SINGH	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN