VELLINTON HEALTHCARE

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	: **METOFOX 5** Metoprolol Injection IP.		
Batch No.	: GA25L-01B	**Mfg. Date**	: 12/2025
Batch Size	: 27550 Ampoules	**Exp. Date**	: 11/2027
Sample Qty.	: 50 Ampoules	**Analytical Report No.**	: AFP20250730
Date of Receiving	: 05/12/2025	**Date of Completion**	: 19/12/2025
Mfg. License No.	: N-MB/18/201		

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless liquid solution filled in 5 ml clear glass ampoule.	Clear colourless liquid solution filled in 5 ml clear glass ampoule.
2.	Identification A (By IR)	Compare the spectrum with that obtained with Metoprolol tartrate WS treated in the same manner or with the reference spectrum of Metoprolol.	Complies
	B (By HPLC)	In the related substances, the principal peak in the chromatogram obtained with the reference solution (a) corresponds to the peak in the chromatogram obtained with reference solution (b).	Complies
	C (By HPLC)	The chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (a).	Complies
3.	Uniformity of filled volume	Not less than nominal volume	Min: 5.0 ml Max: 5.1 ml
4.	Average fill volume	Not less than 5 ml	5.05 ml
5.	pH	5.50 to 7.5	7.04
6.	Related Substances		
	The area of any secondary peak	NMT 0.3 %	Complies
	The sum of areas of all secondary peaks	NMT 0.5 %	Complies
	Metoprolol impurity C	NMT 0.3 %	Complies
7.	Particulate Matter		
	≥ 10µm	NMT 6000 particles/Container	Less than 6000 particles/ Ampoule
	≥ 25µm	NMT 600 particles/Container	Less than 6000 particles/ Ampoule
8.	Sterility	Should be Sterile	Sterile
9.	Bacterial Endotoxins	NMT 25.0 Eu/mg of Metoprolol Tartrate.	Less than 25.0 Eu/mg of Metoprolol
10.	Assay : Each ml contains:-		

Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Metoprolol Tartrate IP	1.0 mg	1.0063 mg	100.63 %	95.0% to 105.0%

Remarks: In the opinion of the undersigned the sample submitted complies/~~does not~~ complies with the prescribed standard/~~not~~ standard of quality, as according to I.P. and IHS with respect to the above test only.

	Prepared By	Checked By	Approved By
Name	**Manisha**	**Punam**	**Anuj Kumar**
Designation	**Sr. Offier (QC)**	**Executive (QC)**	**Asst. Manager (QC)**
Sign/ Date	19/12/2025	19/12/2025	19/12/2025

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