



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : METOFOX 5 Metoprolol Injection IP.	
Batch No. : GA24E -22	Mfg. Date : 05/2024
Batch Size : 11820 Ampoules	Exp. Date : 04/2026
Sample Qty. : 50 Ampoules	Analytical Report No. : AFP20240288
Date of Receiving : 30/05/2024	Date of Completion : 13/06/2024
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.	A 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	6.41	
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 Tartrate.	
10.	Assay : Each ml contains:-			
Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Metoprolol Tartrate IP	1.0 mg	1.01 mg	101.0 %	95.0% to 105%

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

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager in-charge
Signature:- Date:- 13/06/2024	Signature:- Date:- 13/06/2024	Signature:- Date:- 13/06/2024

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