



# VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : Metofox 5 Metoprolol Injection IP.	
<b>Batch No.</b> : GA24H-02A	<b>Mfg. Date</b> : 08/2024
<b>Batch Size</b> : 20180 Ampoules	<b>Exp. Date</b> : 07/2026
<b>Sample Qty.</b> : 45 Ampoules	<b>Analytical Report No.</b> : AFP20240508
<b>Date of Receiving</b> : 09/08/2024	<b>Date of Completion</b> : 23/08/2024
<b>Mfg. License No.</b> : 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	5.03 ml		
5.	pH	5.50 to 7.5	7.34		
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	0.9788 mg	97.88 %	95.0% to 105%

**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.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/ In-charge
Signature:- Date:-	Signature:- Date:-	Signature:- Date:-

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