



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

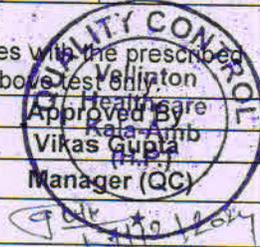
Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : METOFOX 5 Metoprolol Injection IP.	
Batch No. : GA24K-64A	Mfg. Date : 11/2024
Batch Size : 24805 Ampoules	Exp. Date : 10/2026
Sample Qty. : 50 Ampoules	Analytical Report No. : AFP20240744
Date of Receiving : 03/12/2024	Date of Completion : 17/12/2024
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	6.55		
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	1.0079 mg	100.79 %	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.

Name	Prepared By Punam Kumari	Checked By Anuj Kumar	
Designation	Executive	Sr. Executive	
Sign/ Date	<i>[Signature]</i> 17/12/2024	<i>[Signature]</i> 17/12/2024	

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