



# VELLINTON HEALTHCARE

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

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

|                          |                            |                              |               |
|--------------------------|----------------------------|------------------------------|---------------|
| <b>Product Name</b>      | : Metoprolol Injection IP. |                              |               |
| <b>Batch No.</b>         | : GA25I-43A                | <b>Mfg. Date</b>             | : 09/2025     |
| <b>Batch Size</b>        | : 15450 Ampoules           | <b>Exp. Date</b>             | : 08/2027     |
| <b>Sample Qty.</b>       | : 50 Ampoules              | <b>Analytical Report No.</b> | : AFP20250594 |
| <b>Date of Receiving</b> | : 26/09/2025               | <b>Date of Completion</b>    | : 11/10/2025  |
| <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.   | 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<br>Max: 5.1 ml   |                     |                            |
| 4.                     | Average fill volume                     | Not less than 5 ml   | 5.03 ml  |                     |                            |
| 5.                     | pH                                      | 5.50 to 7.5  | 6.58   |                     |                            |
| 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   | 1.0052 mg  | 100.52 %            | 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  |
|--------------------|------------------|--------------------|--------------|
| <b>Name</b>        | Manisha          | Anuj Kumar         | Vikas Gupta  |
| <b>Designation</b> | Sr. Officer (QC) | Asst. Manager (QC) | Manager (QC) |
| <b>Sign/ Date</b>  |                  |                    |              |

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