

# UNITED BIOTECH PVT. LTD.

TEHLIWAL (DHANA) BAGBANIA,  
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GST NO. : 02AAACU1839L1ZE CIN No. : U24239DL1997PTC084814

Mfg.Licence No. : MB/05/255 & MNB/05/254

QUALITY CONTROL DEPARTMENT  
( FINISH )

Sample : TIPLAB 10 ML INJ  
Generic Name: LABETALOL HYDROCHLORIDE INJECTION USP 5M  
: G/ML  
Mfg.&Supp.By: UNITED BIOTECH PVT. LTD.  
Batch No. : LBIC4C1 Mfg.Dt.: Mar., 2024  
Batch Size : 3000 NOS Exp.Dt.: Feb., 2026  
Report No.: FGG-9661024  
Ref. No. : GI-10/141  
Rcpt.Date : 21-10-2024  
Sample Qty: 41 Amps(Controlled Samples)

## CERTIFICATE OF ANALYSIS

Specification No.UB/BS/S/LBIC/02-01 Testing Protocol No.UB/BT/T/LBIC/02-01

| Test Parameter (USP)        | Observed                                                                                                                                                                                               | Standard Limit               |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Description                 | : 10 ml clear and colourless solution filled in 10 ml amber glass ampoule having blue dot. Such 5 ampoules of 10 ml each placed in a plastic tray & packed in a printed mono carton along with insert. |                              |
| Identification By HPLC      | : The retention time of test chromatogram is same as of standard chromatogram.                                                                                                                         |                              |
| pH                          | : 3.88                                                                                                                                                                                                 | 3.0 to 4.5                   |
| Nominal volume              | : 10.0 ml                                                                                                                                                                                              |                              |
| Extractable volume          | : 10.1 ml                                                                                                                                                                                              | NLT 10.0 ml                  |
| Particulate matter          | : Clear & free from particle viewed under unaided eye.                                                                                                                                                 |                              |
| 10µm or greater             | : 286 Particles                                                                                                                                                                                        | NMT 6000 Particles/Container |
| 25µm or greater             | : 82 Particles                                                                                                                                                                                         | NMT 600 Particles/Container  |
| Chromatographic purity      | :                                                                                                                                                                                                      |                              |
| Total Impurities            | : Complies                                                                                                                                                                                             | NMT 1.0%                     |
| Bacterial Endotoxins        | : Less than 1.2 EU/mg                                                                                                                                                                                  | NMT 1.2 EU/mg                |
| Sterility                   | : Passes the test of sterility as per USP.                                                                                                                                                             |                              |
| Assay                       | : Each ml contains :                                                                                                                                                                                   |                              |
|                             | Observed                                                                                                                                                                                               | Claim Limit                  |
| Labetalol Hydrochloride USP | 5.15 mg                                                                                                                                                                                                | 5.0 mg 4.50 mg to 5.50 mg    |

Report : In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the act and the Rules made there under as per USP.

Date: 04-11-2024

Analysed By:

Testing Incharge:

\*\*\* End of Report \*\*\*