

**BILLS BIOTECH PVT. LTD.**

Plot No.-P/01, Biotech Park Phase-1, GIDC, Manjusar Industrial Estate  
Village-Manjusar, Savli-Vadodara-391775

**CERTIFICATE OF ANALYSIS**

|                   |  |              |                          |
|-------------------|--|--------------|--------------------------|
| Product name      | : MUPIROCIN EP   | Spec.ref.no. | : BBL/FPS/BB/FP/04/03-05 |
| Batch no.         | : MUP21-04   | STP ref.no.  | : BBL/FPT/BB/FP/04/03-06 |
| Mfg. date         | : Mar-2021   | A.R. no.     | : BFP/21/03/003          |
| Re-test date      | : Feb-2024   | Batch size   | : 69.530 kgs             |
| Storage condition | : Preserved in air-tight container between 2°C to 8°C, protected from light. |              |                          |

| TESTS                                    | SPECIFICATION   | RESULTS  |
|--|---|--|
| Description                              | A white or almost white powder.   | A white powder.  |
| Solubility                               | Freely soluble in acetone, in anhydrous ethanol. Slightly soluble in water and in dichloromethane. It shows polymorphism  | Freely soluble in acetone, in anhydrous ethanol. Slightly soluble in water and in dichloromethane. It shows polymorphism |
| Identification (By IR)                   | The infrared absorption spectrum of a sample exhibit maxima, which are only at the same wavelength as in the spectrum of mupirocin RS/working standard or with the reference spectrum of mupirocin. | Complies   |
| pH                                       | Between 3.5 and 4.0, in a saturated aqueous solution.   | 3.67   |
| Water content                            | Not more than 1.0 %   | 0.61 %   |
| Specific optical rotation (on dry basis) | Between -17.0° to -21.0 °   | -17.74°  |
| Related Substances (by HPLC)             |   |  |
| Mupirocin impurity C                     | Not more than 4.0 %   | 1.04%  |
| Any other individual impurity            | Not more than 1.0 %   | 0.45 %   |
| Total impurities                         | Not more than 6.0 %   | 2.36 %   |
| Assay (by HPLC)                          | 93.0% to 102.0 %<br>Calculated on the anhydrous basis.  | 99.98 %  |
| Additional test                          |   |  |
| Residual solvent (by GC)                 | Ethyl acetate : NMT 5000 ppm  | 1.80 ppm   |
|  | n-Heptane : NMT 5000 ppm  | 483.15 ppm   |
|  | Acetone : NMT 5000 ppm  | 2617.32 ppm  |

Remarks: The product complies / does not comply above tests as per EP specifications.

|       |                  |                 |                  |
|-------|------------------|-----------------|------------------|
|       | Prepared by (QC) | Checked by (QC) | Approved by (QA) |
| Sign: |                  |                 |                  |
| Date: | 03-05-2021       | 03-05-2021      | 03-05-2021       |