

**BILLS BIOTECH PVT. LTD.**

Plot No.-P/01, Biotech Park Phase-1, Manjusar GIDC, Industrial Estate,
Savli, Vadodara – pin code - 391775, Gujarat, India.

CERTIFICATE OF ANALYSIS

COA No.: COA/FP/MUP25-07/007-06

Product name	: MUPIROCIN EP	Spec.ref.no	: BBL/FPS/BB/FP/04/06-08
Batch no.	: MUP25-07	STP ref.no.	: BBL/FPT/BB/FP/04/06-06
Mfg. date	: Feb-2025	A.R. no.	: BFP/25/02/003
Exp. date	: Jan-2028	Batch size	: 107.040Kg
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	Slightly soluble in water, freely soluble in acetone, in anhydrous ethanol and in methylene chloride.	Complies
Polymorphism	It shows polymorphism (by melting point 82.5° to 86°C)	84.6°C
Identification (By IR)	The infrared absorption spectrum of sample exhibit maxima, which are only at the same wavelength as in the spectrum of Mupirocin RS or working standard or with the reference spectrum of Mupirocin.	Complies
pH	Between 3.5 and 4.0, in a saturated aqueous solution.	3.83
Specific optical rotation	Between -21.0° to -17.0° (on anhydrous substance)	-18.8°
Water by KF	Maximum 1.0 %	0.29 %
Related Substances (by HPLC)		
Mupirocin impurity C	Not more than 4.0 %	1.34 %
Any other impurity	Not more than 1.0 %	0.25 %
Total impurities	Not more than 6.0 %	2.35 %
Assay (by HPLC)	93.0% to 102.0 % Calculated on the anhydrous basis.	99.3 %
Additional test		
Residual solvent (by GC)	Ethyl Acetate : NMT 5000 ppm	77.23ppm
	n-Heptane : NMT 5000 ppm	530.33ppm
	Acetone : NMT 5000 ppm	1657.86ppm

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

Responsibility	Prepared By (QC)	Checked By (QC)	Approved By (QC)	Approved By (QA)
Sign / Date	J.M.P 17-03-2025	[Signature] 17-03-2025	[Signature] 17-03-2025	[Signature] 17-03-2025

METAPHARMACEUTICAL

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