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 % 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

METAPHARMACEUTICAL

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08/09/2021.