

**GUFIC GROUP OF TESTING LABORATORIES**

**METAPHARMACEUTICAL**

N DE LOTE:

**0211224**



*26/12/2024*

**CERTIFICATE OF ANALYSIS**

Product	: <b>Prilocaine EP</b>	QC Ref. No.	: QC-FP-API-24-0159
Batch No.	: AE240117A	Quantity Received	: 163.3 Kg.
Date of Mfg.	: Apr.2024	Sampling Date	: 08/04/2024
Date of Exp.	: Mar.2029	Release Date	: 24/04/2024
Manufacturer	: Gufic Biosciences Limited.	Quantity Sampled	: 25 gm.
Testing Specification No	: SPC/FPR/BD/003	Specification	: EP
CAS No.	: 721-50-6		

TESTS	RESULTS	LIMITS
Appearance	White crystalline powder.	White or almost white, crystalline powder.
Solubility	Slightly soluble in water, very soluble in acetone and in ethanol (96 per cent).	Slightly soluble in water, very soluble in acetone and in ethanol (96 per cent).
Identification By Infrared Spectrophotometry	An IR spectrum of sample is concordant with the standard spectra of working standard of Prilocaine.	An IR spectrum of sample should be concordant with the standard spectra of working standard or reference standard of Prilocaine.
Appearance of solution	Solution is clear and colourless	Solution should be clear and colourless.
Related substances	Impurity B 0 ppm Impurity G 0.00% Unspecified impurity 0.07% Total impurities 0.07%	Not more than 100 ppm Not more than 0.15% Not more than 0.10% Not more than 0.2%
Water	0.13%	Not more than 0.5%
Sulphated Ash	0.07%	Not more than 0.1 %
Assay (Anhydrous Substance)	100.02%	Not less than 99.0% and not more than 101.0%
Residual solvent	Petroleum Ether BDL ppm Acetone 5 ppm Dichloromethane 17 ppm Toluene 3 ppm	NMT 100 ppm NMT 5000 ppm NMT 600 ppm NMT 890 ppm

**REMARK:** This is to certify that above product Complies/ Does not comply with prescribed standard quality of EP 11.2.

**PREPARED BY**

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 Date : 26/04/2024

**CHECKED BY**

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