

METAPHARMACEUTICAL

N DE LOTE:

0020323



03/03/2023

CERTIFICATE OF ANALYSIS

Product	: Prilocaine EP	QC Ref. No.	: QC-FP-API-23-0010
Batch No.	: API/PRB/231002	Quantity Received	: 165 Kg.
Date of Mfg.	: Jan.2023	Sampling Date	: 10/01/2023
Date of Exp.	: Dec.2027	Release Date	: 23/01/2023
Manufacturer	: Gufic Biosciences Limited.	Quantity Sampled	: 25 gm.
Testing Specification No	: SPC/FPR/BD/003	Specification	: EP

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 36 ppm Impurity G 0.00% Unspecified impurity 0.00% Total impurities 0.00%	Not more than 100 ppm Not more than 0.15% Not more than 0.10% Not more than 0.2%
Water	0.05%	Not more than 0.5%
Sulphated Ash	0.06%	Not more than 0.1 %
Assay (Anhydrous Substance)	99.88%	Not less than 99.0% and not more than 101.0%
Residual solvent	Petroleum Ether 30 ppm Acetone 0 ppm Dichloromethane 60 ppm Toluene 0 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 10.2.

PREPARED BY

Name : Mr. Mitul Naik
 Designation : Officer
 Date : 23/01/2023

CHECKED BY

Name : Mr. Vimal Patel
 Designation : Executive
 Date : 23/01/2023

APPROVED BY

Name : Mr. Vinod Singh
 Designation : Manager-QC
 Date : 23/01/2023

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