



CERTIFICATE OF ANALYSIS

Product : Prilocaine EP
 Batch No. : API/PRB/211014
 Date of Mfg. : May, 2021
 Date of Exp. : Apr. 2026
 Manufacturer : Gufic Biosciences Limited.
 Testing Specification No : SPC/FPR/BD/003

QC Ref. No. : QC-FP-API-21-0213
 Quantity Received : 140 Kg.
 Sampling Date : 24/05/2021
 Release Date : 29/05/2021
 Quantity Sampled : 25 gm.
 Specification : EP

18/10/2021

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 45 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%
Heavy Metals	Less than 20 ppm	Not more than 20 ppm
Water	0.14%	Not more than 0.5%
Sulphated Ash	0.04%	Not more than 0.1 %
Assay (Anhydrous Substance)	100.70%	Not less than 99.0% and not more than 101.0%
Residual solvent	Petroleum Ether 15 ppm Acetone 6 ppm Dichloromethane 0 ppm Toluene 3 ppm	NMT 1200 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 10.0

PREPARED BY

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