



CERTIFICATE OF ANALYSIS

Product	: Prilocaine EP	QC Ref. No.	: QC-FP-API-20-0345
Batch No.	: API/PRB/203038	Quantity Received	: 120 Kg.
Date of Mfg.	: Jul.2020	Sampling Date	: 11/07/2020
Date of Exp.	: Jun.2025	Release Date	: 20/07/2020
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	18 ppm	Not more than 100 ppm
	Impurity G	0.00%	Not more than 0.15%
	Unspecified impurity	0.00%	Not more than 0.10%
	Total impurities	0.00%	Not more than 0.2%
Heavy Metals	Less than 20 ppm	Not more than 20 ppm	
Water	0.29%	Not more than 0.5%	
Sulphated Ash	0.04%	Not more than 0.1 %	
Assay (Anhydrous Substance)	99.70%	Not less than 99.0% and not more than 101.0%	
Residual solvent	DCM	118 ppm	Not more than 600 ppm
	Toluene	0 ppm	Not more than 890 ppm

REMARK: This is to certify that above product Complies/ ~~Does not comply~~ with prescribed standard quality of EP 10.0.

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