

**CERTIFICATE OF ANALYSIS**

Product	: Prilocaine EP	QC Ref. No.	: QC-FP-API-18- 0166
Batch No.	: 260	Quantity Received	: 107 Kg.
Date of Mfg.	: May.2018	Sampling Date	: 03/05/2018
Date of Exp.	: Apr.2023	Release Date	: 10/05/2018
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 S is clear and colourless	Solution S should be clear and colourless.
Related substances	Impurity B 0 ppm	Not more than 100 ppm
	Impurity G 0.00%	Not more than 0.15%
	Single Maximum unsecified impurity 0.00%	Not more than 0.10%
	Total impurity 0.00%	Not more than 0.2%
Heavy Metals	Less than 20 ppm	Not more than 20 ppm
Water	0.19%	Not more than 0.5%
Sulphated Ash	0.03%	Not more than 0.1 %
Assay (Anhydrous Substance)	99.80%	Not less than 99.0 per cent and not more than 101.0 per cent
Residual solvent	DCM 0 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 9.0.

PREPARED BY

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