

**CERTIFICATE OF ANALYSIS**

Product	: Prilocaine EP	QC Ref. No.	: QC-FP-API-19- 0036
Batch No.	: 279	Quantity Received	: 165 Kg.
Date of Mfg.	: Feb.2019	Sampling Date	: 06/02/2019
Date of Exp.	: Jan.2024	Release Date	: 18/02/2019
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 Impurity G 0.00% Single Maximum unsecified impurity 0.05% Total impurity 0.10%	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	0.01%	Not more than 0.5%
Sulphated Ash	0.03%	Not more than 0.1 %
Assay (Anhydrous Substance)	100.11%	Not less than 99.0 per cent and not more than 101.0 per cent
Residual solvent	DCM 36 ppm Toluene 7 ppm	Not more than 600 ppm Not more than 890 ppm

REMARK: This is to certify that above product Complies/ ~~Does not~~ comply with prescribed standard quality of EP 9.4.

**PREPARED BY**

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