

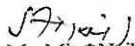


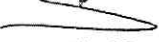
## CERTIFICATE OF ANALYSIS


Product : <b>Prilocaine EP</b>	QC Ref. No. : QC-FP-API-23-0224
Batch No. : API/PRB/231018	Quantity Received : 160 Kg.
Date of Mfg. : May.2023	Sampling Date : 06/05/2023
Date of Exp. : Apr.2028	Release Date : 22/05/2023
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 22 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)	100.20%	Not less than 99.0% and not more than 101.0%
Residual solvent	Petroleum Ether BDL ppm Acetone 13 ppm Dichloromethane 53 ppm Toluene 4 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 11.2.

**PREPARED BY**   
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 Designation : Officer  
 Date : 23/11/2023

**CHECKED BY**   
 Name : Mr. Vimal Patel  
 Designation : Executive  
 Date : 23/11/2023

**APPROVED BY**   
 Name : Mr. Vinod Singh  
 Designation : Manager-QC  
 Date : 23/11/2023

GN-QC-020-F1-01

**METAPHARMACEUTICAL**

N DE LOTE:

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