



ANALYSIS CERTIFICATE

Lot: 0020920

FDA Labeler Code No. 053296

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 19A0270/20

Lot No. : A-190239

Quantity. : 40 KG

ANALYTICAL DATA	SPECIFICATIONS	RESULTS	NOTES
Description	White or almost white crystalline powder	Conforms	
Identification	Test A.- IR, Test B.- HPLC - Assay and Test C.- Chloride identification.	Conforms	
pH	3.5 - 5.5	5.3	
Loss on Drying	MMT 0.5%	0.25 %	
Residue on ignition	MMT 0.1%	Less than 0.05 %	
Chromatographic purity. Impurity MXT-200	MMT 0.10%	0 %	0.00%
Chromatographic purity. Impurity MXT-300.	MMT 0.10%	0 %	0.00%
Chromatographic purity. Any other individual impurity	MMT 0.10%	0 %	0.00%
Chromatographic purity. Total impurities	MMT 1.5%	0.01 %	
Assay	98.0 - 102.0% (on dry basis)	100.1 %	
2,6-Dimethylphenol	MMT 0.1%	Conforms	

Manufacturing Date May 7, 2019

Re-Test date May 7, 2022

15.04.2020
Prepared by16.04.2020
Approved by

Head of Quality Control

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