

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 18A0586/03

Lot No. : A-180559

Quantity. : 30 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	5.4	
Loss on Drying		NMT 0.5%	0.12 %	
Residue on ignition		NMT 0.1%	Less than 0.05 %	
Chromatographic purity. Impurity MXT-200		NMT 0.10%	0 %	Not detected
Chromatographic purity. Impurity MXT-300.		NMT 0.10%	0 %	Not detected
Chromatographic purity. Any other individual impurity		NMT 0.10%	0 %	
Chromatographic purity. Total impurities		NMT 1.5%	0.01 %	
Assay		98.0 - 102.0% (on dry basis)	99.8 %	
2,6-Dimethylphenol		NMT 0.1%	Conforms	

Manufacturing Date November 15, 2018
Re-Test date November 15, 2021



11.04.19
Prepared by



Approved by

Head of Quality Control

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