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ANALYSIS CERTIFICATE

PRODUCT: MEXILETINE HCl USP

FDA Labeler Code No. 053296

Certificate of Analysis No. : 19A0267/03 Lot No. : A-190233 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	5.2	
Loss on Drying	NMT 0.5%	0.10 %	
Residue on ignition	NMT 0.1%	Less than 0.05 %	
Chromatographic purity. Impurity MXT-200	NMT 0.10%	0 %	0.00%
Chromatographic purity. Impurity MXT-300.	NMT 0.10%	0 %	0.00%
Chromatographic purity. Any other individual impurity	NMT 0.10%	0 %	0.00%
Chromatographic purity. Total impurities	NMT 1.5%	0.01 %	
Assay	98.0 - 102.0% (on dry basis)	100.1 %	
2,6-Dimethylphenol	NMT 0.1%	Conforms	

Manufacturing Date May 6, 2019
Re-Test date May 6, 2022

Pilar 24.10.19

Prepared by

P.O. 24.10.19

Approved by

Head of Quality Control

Printed date: October 24. 2019

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