



ANALYSIS CERTIFICATE

FDA Labeler Code No. 053296

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 18A0403/06

Lot No. : A-180400

Quantity. : 30 KG

ANALYTICAL DATA	SPECIFICATIONS	RESULTS	NOTES
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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	NMT 0.5%	0.15 %	
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 %	0.00%
Chromatographic purity. Any other individual impurity	NMT 0.10%	0.02 %	
Chromatographic purity. Total impurities	NMT 1.5%	0.03 %	
Assay	98.0 - 102.0% (on dry basis)	99.2 %	
2,6-Dimethylpheno1	NMT 0.1%	Conforms	

Manufacturing Date August 1, 2018

Re-Test date August 1, 2021

03/10/18
Prepared by

03.10.18
Approved by

Head of Quality Control

Printed date: October 03. 2018

Offices: Fructuós Gelabert, 6-8
08970 Sant Joan Despi. Barcelona, Spain
Tel.: +34 93 477 64 40
Fax: +34 93 477 64 44

Factory: Polígono Industrial de Celrà
17460 Celrà, Girona, Spain
Tel.: +34 972 49 22 26
Fax: +34 972 49 22 29

e-mail: info@medichem.es
www.medichem.es