



ANALYSIS CERTIFICATE

Lot: 0250617

FDA Labeler Code No. 053296

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 17A0303/01

Lot No. : A-170279

Quantity. : 10 KG

ANALYTICAL DATA		SPECIFICATIONS	RESULTS	NOTES
Description	White or almost white crystalline powder.		Conforms	
Identification	Test A.- IR, Test B.- HPLC and Test C.- Chloride identification.		Conforms	
pH	3.5 - 5.5		5.3	
Loss on Drying	NMT 0.5%		0.20 %	
Residue on ignition	NMT 0.1%		Less than 0.05 %	
Heavy Metals	NMT 10 ppm		Conforms	
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%		0.01 %	
Chromatographic purity. Total impurities	NMT 1.5%		0.01 %	
Assay	98.0 - 102.0% (on dry basis)		99.7 %	
2,6-Dimethylphenol	NMT 0.1%		Conforms	

Manufacturing Date June 1, 2017

Re-Test date June 1, 2020

27.06.17

Analyst

Head of Quality Control

Printed date: June 27. 2017

Offices: Fructuós Gelabert, 6-8
08970 Sant Joan Despí. 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