medichem

ANALYSIS CERTIFICATE

Lote: 002/213

FDA Labeler Code No. 053296

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 13A0359/02 Lot No. : A-130339 Quantity. : 10 KG

ANALYTICAL DATA	SPECIFICATIONS	RESULTS	NOTES
Description	White or almost white crystalline powder.	Conforms	
Identification	Test A.- I.R., Test B-. TLC and Test C.- Ch	Conforms	
pH	3.5 - 5.5	5.4	
Loss on Drying	NMT 0.5%	Less than 0.05 %	
Residue on ignition	NMT 0.1%	Less than 0.05 %	
Heavy Metals	NMT 0.001% (Pb)	Conforms	
Chromatographic purity. Any individual impurity	NMT 1.0%	0.02 %	
Chromat. Purity. Total impurities	NMT 1.5%	0.03 %	
Assay	98.0 - 102.0% (on dry basis)	100.3 %	

Manufacturing Date October 10, 2013

Re-Test date October 10, 2016

28.11.13

Analyst

28.11.13

Quality Control Manager

Printed date: November 28. 2013

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