



ANALYSIS CERTIFICATE

Lot: 0061114

PRODUCT: MEXILETINE HCl USP

FDA Labeler Code No. 053296

Certificate of Analysis No. : 14A0202/09

Lot No. : A-140146

Quantity. : 9.35 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	(solution 1 in 10)		
	NMT 0.5%	0.24 %	
Residue on ignition	NMT 0.1%	Less than 0.05 %	
Heavy Metals	NMT 0.001%	Conforms	
Chromatographic purity. Any individual impurity	NMT 1.0%	0.04 %	
Chromatographic purity. Total impurities	NMT 1.5%	0.09 %	
Assay	98.0 - 102.0%	100.1 %	
2,6-Dimethylphenol	NMT 0.1%	Conforms	

Manufacturing Date April 23, 2014

Re-Test date April 23, 2017

3.0745

Analyst

Quality Control Manager

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