



ANALYSIS CERTIFICATE

PRODUCT: MEXILETINE HCl USP

FDA Labeler Code No. 053296

Certificate of Analysis No. : 14A0049/03

Lot No. : A-140037

Quantity. : 10 KG

ANALYTICAL DATA

SPECIFICATIONS

RESULTS

NOTES

Description

White or almost white
crystalline powder.

Conforms

Identification

Test A.- IR, Test B.- TLC,
and Test C.- Chlorides

Conforms

pH

3.5 - 5.5 (solution 1 in 10)

5.1

Loss on Drying

NMT 0.5%

0.09 %

Residue on ignition

NMT 0.1%

Less than 0.05 %

Heavy Metals

NMT 0.001%

Conforms

Chromatographic purity. Any individual
impurity

NMT 1.0%

0.02 %

Chromatographic purity. Total impurities

NMT 1.5%

0.07 %

Assay

98.0 - 102.0% (on dry basis)

98.6 %

Manufacturing Date February 7, 2014

Re-Test date February 7, 2017

28.08.14

Analyst

Quality Control Manager

Printed date: August 28, 2014

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