

PRODUCT : MEXILETINE HCl USP

Certificate of Analysis No. : 11A0332/09

Lot No. : A-110299

Quantity. : 5 Kg

ANALYTICAL DATA

SPECIFICATIONS

RESULTS

NOTES

Description

White or almost white
crystalline powder.

Conforms

Identification

A.- I.R.

Conforms

B.- TLC

C.- Chlorides

pH

3.5 - 5.5

5.0

Loss on Drying

NMT 0.5%

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 %

0.00%

Chromatographic purity. Total impurities

NMT 1.5%

0.01 %

Assay

98.0 - 102.0% (on dry basis)

100.0 %

Manufacturing Date September 5, 2011

Re-Test date September 5, 2014

Analyst

Quality Control Manager

Printed date: July 09, 2012

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