

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 13A0090/03

Lot No. : A-130071

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

5.0

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%

0.01 %

Chromat. Purity. Total impurities

NMT 1.5%

0.02 %

Assay

98.0 - 102.0% (on dry basis)

100.1 %

Manufacturing Date February 19, 2013

Re-Test date February 19, 2016

Analyst

Quality Control Manager

Printed date: March 06, 2013

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