

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 16A0265/07

Lot No. : A-160255

Quantity. : 10 KG

ANALYTICAL DATA

SPECIFICATIONS

RESULTS

NOTES

Description

White or almost white
crystalline powder.

Conforms

Identification

Test A.- IR, Test B.-. HPLC

Conforms

and Test C.- Chloride identification

pH

3.5 - 5.5

5.1

Loss on Drying

NMT 0.5%

0.21 %

Residue on ignition

NMT 0.1%

Less than 0.05 %

Heavy Metals

NMT 10 ppm

Conforms

Chromatographic purity. Impurity MXT-200

NMT 0.10%

Not detected

Chromatographic purity. Impurity MXT-300.

NMT 0.10%

0.00%

Chromatographic purity. Any other
individual impurity

NMT 0.10%

0.03 %

Chromatographic purity. Total impurities

NMT 1.5%

0.03 %

Assay

98.0 - 102.0% (on dry basis)

101.1 %

2,6-Dimethylphenol

NMT 0.1%

Conforms

Manufacturing Date June 9, 2016

Re-Test date June 9, 2019



23.10.17

Analyst

Head of Quality Control

Printed date: October 20. 2017

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