

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. :

15A0216/19

Lot No. :

A-150204

Quantity. : 10 KG

FDA Labeler Code No. 053296

lot: 031115

lot: 00000016 ylu 31/08

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

5.4

(solution 1 in 10)

Loss on Drying

MT 0.5%

0.07 %

Residue on ignition

MT 0.1%

Less than 0.05 %

Heavy Metals

MT 0.001%

Conforms

Chromatographic purity. Any individual impurity

MT 1.0%

0.04 %

Chromatographic purity. Total impurities

MT 1.5%

0.12 %

Assay

98.0 - 102.0%(on dry basis)

99.5 %

2,6-Dimethylphenol

MT 0.1%

Conforms

Manufacturing Date May 19, 2015

Re-Test date May 19, 2018

Analyst

Quality Control Manager

Printed date: August 24, 2016

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