



ANALYSIS CERTIFICATE

PRODUCT: MEXILETINE HCl USP

FDA Labeler Code No. 053296

Certificate of Analysis No. : 15A0216/22

Lot No. : A-150204

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

5.4

(solution 1 in 10)

Loss on Drying

NMT 0.5%

0.07 %

Residue on ignition

NMT 0.1%

Less than 0.05 %

Heavy Metals

NMT 0.001%

Conforms

Chromatographic purity. Any individual impurity

NMT 1.0%

0.04 %

Chromatographic purity. Total impurities

NMT 1.5%

0.12 %

Assay

98.0 - 102.0%(on dry basis)

99.5 %

2,6-Dimethylphenol

NMT 0.1%

Conforms

Manufacturing Date May 19, 2015

Re-Test date May 19, 2018

Analyst

Quality Control Manager

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