



ANALYSIS CERTIFICATE

Lot: 06.11.14

FDA Labeler Code No. 053296

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No.: 14A0202/06

Lot No.: A-140146

Quantity.: 10 KG

ANALYTICAL DATA

SPECIFICATIONS

RESULTS

NOTES

Description

White or almost white
crystalline powder.

Conforms

Identification

Test A.- IR, Test B.- TLC,
and Test C.- Chlorides

Conforms

pH

3.5 - 5.5 (solution 1 in 10)

5.3

Loss on Drying

NMT 0.5%

0.24 %

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%

0.09 %

Assay

98.0 - 102.0% (on dry basis)

100.1 %

Manufacturing Date April 23, 2014

Re-Test date April 23, 2017

Analyst

Quality Control Manager

Printed date: November 06, 2014

Offices: Fructuós Gelabert, 6-8
08970 Sant Joan Despí, Barcelona, Spain
Tel.: +34 93 477 64 40
Fax: +34 93 477 64 44Factory: Polígono Industrial de Celrà
17460 Celrà, Girona, Spain
Tel.: +34 972 49 22 26
Fax: +34 972 49 22 29e-mail: info@medichem.es
www.medichem.es