

NORTEC QUÍMICA

CERTIFICATE OF ANALYSIS	Quality Control	Code: 300100017	
		Rev.: 08	Page 1/ 1
PRILOCAINE HYDROCHLORIDE	Batch number: 104513	Reference: EP 5 rd Ed, page 2307 ★ USP 29, page 1797	
	Manuf. Date: APRIL/2011	Expiry Date: APRIL/2016	

TESTS	RESULTS	SPECIFICATIONS
. Description	. White crystalline powder,	. White crystalline powder or colourless crystals. Odourless.
. Solubility	. Water: conforms . Alcohol: conforms . Acetone: conforms . ★ Chloroform: conforms . ★ Ether: conforms	. Freely soluble in water and in alcohol; very slightly soluble in acetone. . Slightly soluble in chloroform; practically insoluble in ether.
. Identification I.R. ★ Melting point Chloride TLC	. Conforms . 168.6°C . Conforms . Conforms	. Conforms to standard . 166°C to 169°C . Positive . Conforms to Standard
. Appearance of Solution	. Conforms (0.75 NTU)	. Solution is clear and colourless
. Optical Rotation (20°C, 10cm)	. 0°C	. - 0.10° to + 0.10°
. Acidity or Alkalinity	. Conforms	. Conforms
. Related Substances (HPLC) Individual Impurity	. < 0.2%	. Not more than 0.2% and only one impurity > 0.1% and < 0.2%
Total impurity	. < 0.5%	. Not more than 0.5%
. O-Toluidine (HPLC)	. < 100 ppm	. Not more than 100 ppm
. Sulphated Ash	. 0.0%	. Not more than 0.1%
. Heavy Metals (as Pb)	. < 20 ppm	. Not more than 20 ppm
. ★ Loss on Drying (1g, 105°C/ 4h)	. 0.0%	. Not more than 0.5%
. Assay (Potenciometric)	. 99.8%	. 99.0% to 101.0%, on the anhydrous basis
. Residual Solvents Acetone Hexane Toluene	. < 1000 ppm . < 29 ppm . < 89 ppm	. Not more than 5000 ppm . Not more than 290 ppm . Not more than 890 ppm

Package and Storage: Keep in a well-closed container, protected from light, at a temperature below 35°C

29.950.060/0001-57	Approved by Quality Control Department Code 04/11-2529, date 04/27/2011
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NORTEC QUÍMICA S.A

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Distrito Ind. Caxias - CEP 25250-000

DUQUE DE CAXIAS - RJ

Corresponde al lote
L11060291 de
Fapron Ibérica.