

CERTIFICATE OF ANALYSIS	Quality Control		Code: 300100025
			Rev.: 09
			Page 1/ 1
PRILOCAINE	Batch number:	Reference:	
	310689	EP 7.3 th Ed., page 3995	
	Manuf. Date:	Expiry data:	
	OCTOBER/2013	OCTOBER/2018	

TESTS	RESULTS	SPECIFICATIONS
Description	. Almost white, crystalline powder	. White or almost white, crystalline powder.
Solubility	. Water: Conforms . Acetone: Conforms . Ethanol: Conforms	. Slightly soluble in water; very soluble in acetone and in ethanol (96%).
Identification Infrared	. Conforms	. Conforms to standard
Appearance of Solution (3.0 NTU)	. Conforms (2.7 NTU)	. Solution is clear and colourless
Related Substances (HPLC)		
Impurity B	. 9 ppm	. Not more than 100 ppm
Unspecified Impurity	. <0.10%	. Not more than 0.10%
Total impurity	. <0.1%	. Not more than 0.2%
Heavy Metals (as Pb)	. <20 ppm	. Not more than 20 ppm
Water (K.F.)	. 0.1%	. Not more than 0.5%
Sulphated Ash	. 0.0%	. Not more than 0.1%
Assay	. 100.5%	. 99.0% to 101.0% (on anhydrous basis)
Residual Solvents (GC)		
Acetone	. <500 ppm	. Not more than 5000 ppm
Hexane	. <29 ppm	. Not more than 290 ppm
Toluene	. <89 ppm	. Not more than 890 ppm

Package and Storage: Keep the recipient hermetically closed and avoid temperature higher than 30 °C

Approved by Quality Control Department
code 10/13-13121, date 10/22/2013

Address: Rua 17 nº 200 Distrito Industrial de Duque de Caxias – Xerém – Duque de Caxias-RJ- Brasil – CEP: 25250-000 – Tel: + 55 21 3651-7300 – Fax: + 55 21 3651-7324

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fragon:
13K05-B09
Director Técnico