Bupivacaine Hydrochloride

asence Pharma Private Limited
Reg, Office : Sarabhai Campus, Dr. Vikram Sarabhai Marg, Wadi Wadi, Vadodara 390 023, India.
Phone : +91-265-2323179 Website : www.asence.com
CIN Number: U24230 GJ2004 PTC045141

CERTIFICATE OF ANALYSIS

Name of Product: Bupivacaine Hydrochloride

Batch No.: 15J56B03

A.R.No.- FP/BUP/QC/022/15-16

Date of Mfg. : Sep 2015

Date of Expiry : Aug 2020

Sr. No.	TESTS	OBSERVATIONS	STANDARDS	Method Reference
1.	Appearance	White crystalline powder	White or almost white, crystalline powder or colourless crystals.	EP
2.	Solubility	Soluble in water, freely soluble in ethanol (96%)	Soluble in water, freely soluble in ethanol (96%).	EP
3.	Identification (First Identification test A, D & E, Second Identification Test B,C D & E)			
	I.R. Spectrum	The infrared absorption spectrum of the sample is concordant with the spectrum of Bupivacaine hydrochloride standard.	The infrared absorption spectrum of the sample should be concordant with the spectrum of Bupivacaine hydrochloride standard.(TestA)	EP (2.2.24)
	Chlorides	Complies	It gives positive Reaction of chloride.(Test D)	EP(2.3.1)
	Optical rotation	0.00^0	-0.10^0 to $+0.10^0$ (Test E)	EP (2.2.7)
4.	Appearance of solution	The solution is clear and colourless	A 2% w/v solution in carbondioxide free water should be clear and colourless.	EP(2.2.1) & (2.2.2, Method II)
5.	Acidity or Alkalinity	Complies	To 10 ml of solution S add 0.2 ml of 0.01 M sodium hydroxide; the pH is not less than 4.7. Add 0.4 ml of 0.01 M hydrochloric acid; the pH is not greater than 4.7.	EP(2.2.3)
6.	Optical rotation	0.00^0	-0.10^0 to $+0.10^0$	EP (2.2.7)

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7.	Related substances (By Gas Chromatography)			EP(2.2.28)
	Impurity B	Below detection limit	Ratio is not greater than 0.5 %	
	Unspecified impurities	0.03 %	Ratio is not greater than 0.10 %	
	Total Impurities	0.03 %	Ratio is not greater than 1.0 %	
8.	Impurity-F (2,6 Dimethyl aniline) by Liquid Chromatography)	0.82 ppm	Not more than 10 ppm	EP (2.2.29)
9.	Heavy metals	Less than 10 ppm	Not more than 10 ppm	EP(2.4.8)
10.	Loss on drying (at 105°C)	5.11 %	Between 4.5% and 6.0 %	EP(2.2.32)
11.	Sulphated ash	0.05 %	Not more than 0.1 %	EP(2.4.14)
12.	Assay (on dried basis)	99.44 %	Not less than 98.5 % and not more than 101.0 %	EP
	Additional Test			
13.	Residual Solvent			
	Isopropyl alcohol	6 ppm	Not more than 5000 ppm	In house
Conclusion: The sample complies with EP-8 Specifications.				

Prepared By :	Checked By :	Approved By (GM-Quality) :
Date : 30.09.2015	Date : 30.09.2015	Date : 30.09.2015

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
15J 30-B02
Director Técnico