

Quality Control Department
CERTIFICATE OF ANALYSIS

LOT: 0/403/2

Product : Lidocaine EP
Batch No. : 1283
Date of Mfg. : Sept.2011
Date of Exp. : Aug.2016
Manufacturer : Gufic Biosciences Limited.
Testing Specification : API/L/02/QC
No.

QC Ref. No. : BD/ 3344
Quantity Manufactured : 400 Kg
Sampling Date : 21/9/2011
Release Date : 24/9/2011
Quantity Sampled : 25 gm
Specification : EP

TESTS	RESULTS	LIMITS
Description	A white crystalline powder.	A white or almost white crystalline powder.
Solubility	Practically insoluble in water, very soluble in ethanol (96%) and in methylene chloride.	Practically insoluble in water, very soluble in ethanol (96%) and in methylene chloride.
Identification	A: By IR: The transmission minima in the spectrum obtained with the substance examined correspond in position and relative size to those in the spectrum obtained with the reference substance. B: Melting point 68°C to 69°C C: A green colour develops.	The transmission minima in the spectrum obtained with the substance to be examined should correspond in position and relative size to those in the spectrum obtained with the reference substance. Between 66°C and 70°C A green colour should develop.
Related Substances By HPLC	Impurity A: 0.000% Unspecified impurities: 0.00% Total impurities: 0.00%	Not more than 0.01 % Not more than 0.1 % Not more than 0.5 %
Chlorides	Less than 35 ppm	Not more than 35 ppm
Sulphates	Less than 0.10%	Not more than 0.1 %
Water	0.10%	Not more than 1.0 % w/w
Sulphated Ash	0.048%	Not more than 0.1 %
Assay	99.90%	99.0 to 101.0 % (on anhydrous basis)
Residual Solvent	Acetone 3302.49 ppm Toluene 717.88 ppm	Not More Than 5000 ppm Not More Than 890 ppm
Bulk Density	: 0.61gm/ml	0.5 to 0.7gm/ml
Particle size	: 90% < 1000microns.	

REMARK: This is to certify that above product Complies/ Does not comply with prescribed standard quality of EP.

ANALYSED BY K. C. Patel
Name Mr. Kalpesh Patel
Designation Chemist Q.C.
Date 24/9/2011

APPROVED BY [Signature]
Name Mr. T.A. Patel
Designation Executive-QC
Date 24/9/2011