

ALCON BIOSCIENCES PRIVATE LIMITED

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Plant:

A-1/2104, Phase III, GIDC - Vapi, Gujarat - 396 195, India.

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CERTIFICATE OF ANALYSIS

lote: 0080611.

Product Name	LIDOCAINE HCL EP 6			
Quantity	1000.00 KGS	Batch No.	ALC/LH/110304	
Mfg. Date	MAR 2011	Exp.Date	FEB 2016	

RESULT OF ANALYSIS

TEST	SPECIFICATION	RESULTS
Description	A white or almost white crystalline powder	A white, crystalline powder.
Solubility	Very soluble in water, freely soluble in ethanol (96%).	Very soluble in water, freely soluble in ethanol (96%).
Identification	 A) Melting point-Between 74°C and 79°C B) IR spectrum-Should be concordant with working standard. C) Colour test-A green colour is produced D)Chloride test-Should be positive 	A) Melting point-78°C B) IR spectrum-Concordant with working standard.
Appearance of solution		Clear and Colourless.
PH (0.5% aqueous solution)	Between 4.0 and 5.5	5.13
Related substances (By HPLC)	Impurity A-Not more than 0.01% Single unknown impurity-Not more than 0.1% Total impurity-Not more than 0.5%	Impurity A-Nil Single unknown impurity- 0.0479% Total impurity-0.105%
Heavy metals Not more than 5 ppm		Less than 5 ppm
Water (By K/F)	Between 5.5% and 7.0%w/w	6.90%
Sulphated ash	Not More Than 0.1%w/w	0.040%
Assay (By Titration)	Not less than 99.0% and not more than 101.0% (on anhydrous basis)	99.45%

Remarks: The above product complies to the standard quality & complies as per Specification.

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Authorised Signatory