





ALCON BIOSCIENCES PRIVATE LIMITED

ISO 9001 - 2000

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Plant:

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

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CERTIFICATE OF ANALYSIS

lote 2.1: 0/8/11/0.

Product Name Ouantity	LIDOCAINE BASE EP 6		
	300 KGS	Batch No.	ALC/LB/100405
Mfg. Date	APR 2010	Exp. Date	MAR 2015

RESULT OF ANALYSIS

TESTS	SPECIFICATION	RESULTS
Description	White or almost white crystalline powder.	Almost white crystalline powder.
Solubility	Very soluble in (96%)& methylene chloride. Practically insoluble in water	Very soluble in (96%)& methylene chloride. Practically insoluble in water
Identification	A)I.R. spectrum: Should be concordant with working standard B)Melting point:66° to 70°C C) Colour test: A green colour develops	A)I.R. spectrum:Concordant with working standard B)Melting point:67°C C) Colour test: A green colour develops
Related substances (By HPLC)	Impurity A-Not more than 0.01% Single unknown impurity-Not more than 0.1% Total impurities-Not more than 0.5%	Impurity A-Nil Single unknown impurity-0.061% Total impurities-0.075%
Chlorides	Not more than 35ppm	Less than 35ppm
Sulphates	Not more than 0.1%	Less than 0.1%
Water(By K/F)	Not more than 1.0%	0.36%
Sulphated ash	Not more than 0.1%	0.060%
Assay (by Titration)	Not less than 99.0% and not more than 101.0%(Calculated on anhydrous basis)	99.70%

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

For ALCON BIOSCIENCES PVT. LTD.

Authorised Signatory