



# ALCON BIOSCIENCES PRIVATE LIMITED



ISO 9001 - 2000

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## CERTIFICATE OF ANALYSIS

Lot 0010114

Product Name	LIDOCAINE HCL EP 7		
Quantity	775.00 KGS	Batch No.	LDH/113040
Mfg. Date	AUG 2013	Exp. Date	JUL 2018

## RESULT OF ANALYSIS

TESTS	SPECIFICATION	OBSERVATION
Description	White or almost white, crystalline powder.	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 to 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. C) Colour Test: A green colour is produced. D) Chloride test: Positive.
Appearance of solution	The solution S is clear and colourless.	Solution is clear and colourless.
pH	Between 4.0 and 5.5	4.87
Related substances (By HPLC)	Impurity A: Not More Than 0.01% Unspecified Impurities: Not More Than 0.10% Total Impurities: Not More Than 0.5%	0.001% 0.02% 0.04%
Heavy metals	Not More Than 5 ppm	Less Than 5 ppm
Water content	Between 5.5% and 7.0% w/w	6.74% w/w
Sulphated ash	Not More Than 0.1% w/w	0.03% w/w
Assay (By Titration)	Not Less Than 99.0% and not more than 101.0% (anhydrous substance)	99.86%

**Remarks:** The above product complies to the standard quality & complies as per EP7 Specification

For ALCON BIOSCIENCES PVT. LTD.

Authorised Signatory