

ALCON BIOSCIENCES PRIVATE LIMITED

ISO 9001 - 2000

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CERTIFICATE OF ANALYSIS

LTE: 016/013

Product Name	LIDOCAINE HCL EP 7		
Quantity	1000.00 KGS	Batch No.	LDH/113024
Mfg. Date	JUN 2013	Exp. Date	MAY 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	4.75
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%	Not Detected 0.08%% 0.15%
Heavy metals	Not More Than 5 ppm	Less Than 5 ppm
Water content	Between 5.5% and 7.0% w/w	6.51% 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)	99.08%

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

For ALCON BIOSCIENCES PVT. LTD

[Signature]
Authorised Signatory