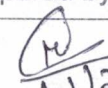
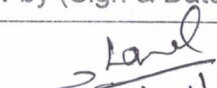



SPECIFICATION	Spec No.: SPE/PRI/FP/001-00	Effective Date : 03/01/2020
	Supersedes : NA	Review Date : 02/01/2022
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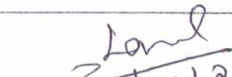
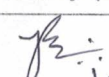
Sr. No	Test	Specification
1.0	Description	Almost white to white crystalline powder
2.0	Solubility	Slightly soluble in water, very soluble in acetone and in ethanol
3.0	Identification	
	By IR	The Infra-red absorption spectrum of sample should be concordant with the standard spectra of working standard of Prilocaine
4.0	Appearance of solution	Solution S should be clear and colourless
5.0	Water content by KF (%w/w)	Not more than 0.5%
6.0	Sulphated Ash (%w/w)	Not more than 0.1% w/w
7.0	Heavy metals	Not more than 20 ppm
8.0	Related substances by HPLC	
	Impurity-B	Not more than 100 ppm
	Impurity-G	Not more than 0.15%
	Single maximum unknown impurity	Not more than 0.10%
	Total impurity	Not more than 0.20%
9.0	Assay by HPLC (%w/w) On Anhydrous basis	Between 99.0% to 101.0%
10.0	Residual solvents (ppm)	
	n-Hexane	Not more than 290 ppm

❖ Remark :

Prepared by (Sign & Date)	Review by (Sign & Date)	Approved by (Sign & Date)
 03/01/2020	 03/01/2020	 03/01/2020

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❖ History of revision :		
Revision No	Effective Date	Details
00		Original issue

Prepared by (Sign & Date)	Review by (Sign & Date)	Approved by (Sign & Date)
 03/01/2020	 03/01/2020	 03/01/2020