


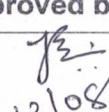
<b>Specification For Finished Product</b>	<b>Spec No.:</b> SPE-LCF-FP-001-01	<b>Effective Date:</b> 12/08/2021
	<b>Supersedes :</b> NA	<b>Review Date:</b> 11/08/2023
	<b>Material code :</b> NA	<b>Reference :</b> In-house
<b>Product Name :</b> Levocloperastine Fendizoate		<b>Page No.:</b> 1 of 1

Sr. No	Test	Specification
1.0	Description	Almost white to white crystalline powder
2.0	Solubility	Soluble in DMF, Insoluble in water
3.0	Identification	
3.1	By IR	The IR Absorption Spectrum of the sample must be concordant with the Standard
3.2	By Melting point	Between 181.0°C to 184.0°C
4.0	Loss on drying (%w/w)	Not more than 0.5% w/w
5.0	Specific optical rotation (C=1.5% in DMF)	Between -2.0° to -8.0°
6.0	Sulphated Ash (%w/w)	Not more than 0.2% w/w
7.0	Related substances by HPLC	
7.1	Single maximum unknown impurity	Not more than 0.5%
7.2	Total impurity	Not more than 1.0%
8.0	Assay by HPLC (%w/w) On Dried basis	Between 98.0% to 102.0%
9.0	Residual solvents (ppm)	
9.1	Methanol	Not more than 3000 ppm
9.2	Acetone	Not more than 5000 ppm
9.3	Ethyl Acetate	Not more than 5000 ppm
9.4	Toluene	Not more than 890 ppm

**Remark:** NA

**History of revision :**

Revision No	Effective Date	Details
00	12/08/2021	Original issue

Prepared by (Sign & Date)	Review by (Sign & Date)	Approved by (Sign & Date)
 12/08/2021	N.D. Patel 12/08/2021	 12/08/2021