COCREATE GLOBAL TECHNOLOGIES PRIVATE LIMITED
U21009KA2023PTC179006
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CERTIFICATE OF ANALYSIS

Product Name - Fexofenadine Hydrochloride

S. No	Test	Specification	Result
1	Description	White to off-white powder.	White powder.
2	Solubility	Freely soluble in methanol, very slightly to slightly soluble in water, very slightly soluble in acetone.	Complies
3	Identification		
	a) By IR	The infrared absorption spectrum of the preparation of the test sample shall exhibit maxima only at the same wavelengths as that of similar preparation of Fexofenadine HCl working standard	Complies
	b) HPLC	The retention time of the Fexofenadine peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies
	c) Content of chloride	A white precipitate should be formed.	Complies
4	Water by KF	Not more than 2.0% w/w	0.63%
5	Residue on ignition	Not more than 0.1% w/w	0.07%
6	Fexofenadine related compound – B (By HPLC)	Not more than 0.20%	Not Detected
7	Other organics impurities by HPLC		
	Fexofenadine Related Compound - A	Not more than 0.2%	0.03%

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	Decarboxylated degradant	Not more than 0.15%	0.02%
	Any other individual, unidentified impurity	Not more than 0.1%	0.07%
	Total impurities	Not more than 0.5%	0.25%
8	Content of Chloride	6.45% - 6.75% on anhydrous basis	6.63%
9	Assay by HPLC (On anhydrous basis)	Not Less than 98.0% and Not more than 102.0% w/w	99.6%

Remarks: The product conforms to the USP Specification.
Storage conditions: Preserve in well-closed, light-resistant containers, and store at controlled room temperature.

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