



Specification For Finished Product	Spec No.: SPE-DEF-FP-001-01	Effective Date : 02/08/2021
	Supersedes : NA	Review Date : 01/08/2023
	Material code : NA	Reference : In-house
Product Name :	Deferasirox	Page No.: 1 of 2



Sr. No	Test	Specification
1.0	Appearance	White to off-white fine powder
2.0	Solubility	Freely soluble in Ethanol, Dimethyl sulfoxide and Dimethyl Formamide. Deferasirox is sparingly soluble in water.
3.0	Identification	
3.1	By IR	The Infra-red absorption spectrum of sample should be concordant with the reference spectrum.
3.2	By HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution.
4.0	Water content (% w/w)	Not more than 0.5%
5.0	Residue on ignition %w/w	Not more than 0.1%
6.0	Related Substances (%area)	
6.1	Salicylamide	Not more than 0.15%
6.2	4-Hydrazinylbenzoic Acid	Not more than 0.15%
6.3	Unspecified Impurity	Not more than 0.1%
6.4	Total impurity	Not more than 1.0%
7.0	Assay on Anhydrous basis %w/w	Not less than 98.0% and Not more than 102.0%
8.0	Residual solvents (ppm)	
8.1	Methanol	Not more than 3000
8.2	Toluene	Not more than 890
8.3	Dichloromethane	Not more than 600

Prepared by (Sign & Date)	Reviewed by (Sign & Date)	Approved by (Sign & Date)
 02/08/2021	N.S. Patel 02/08/2021	 02/08/2021

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Remark: NA

History of revision :		
Revision No	Effective Date	Details
00	02/08/2021	Original issue

Prepared by (Sign & Date)	Reviewed by (Sign & Date)	Approved by (Sign & Date)
 02/08/2021	N. D. Patel 02/08/2021	 02/08/2021