GPO COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Deferasirox (Item No. 41010425)	**Spec. No.** : SP-AK30-D37
Reference(s) : GPO, R&D Institute spec. (RMS-RA-79N54180-01, Rev. No. 00)	**Rev. No.** : 01
Other Requirements : 1. USP 39, ICH (Q6A), (Q3A) 2. In-house Specification from Neuland Laboratories Ltd. /India.	**Page** : 1/2

GPO specification

Test Items	Specification	
Description	Off-white to pale yellow color powder.	
Solubility	Soluble in dimethylformamide and slightly soluble in methanol.	
Identification A. Infrared absorption B. HPLC C. X-ray diffraction (XRPD)	 Conforms to IR standard spectrum. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. The X-ray diffractogram of the sample should match with the Deferasirox (Form-I).	
Loss on drying	Not more than 0.5%.	
Residue on ignition	Not more than 0.1%.	
Heavy metals	Not more than 10 ppm, Method II.	
Related substances	Unspecified individual impurity	: Not more than 0.05%.
	Total impurities	: Not more than 0.30%.
Assay	98.0% - 102.0% w/w of Deferasirox ($C_{21}H_{15}N_3O_4$), calculated on the dried basis.	
Residual solvents	Methylene chloride	: Not more than 600 ppm.
	Toluene	: Not more than 890 ppm.
	Ethanol	: Not more than 5000 ppm.
	Methanol	: Not more than 3000 ppm.
	Isopropyl alcohol	: Not more than 5000 ppm.
Particle size - Laser diffraction, Malvern d (0.9)	Not more than 10 µm.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 23/04/18	S. Tanthithanawat 24/04/18	VARAPIN, 24/04/18	(Acting) 25/04/18	01/05/18
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Deferasirox (Item No. 41010425).
Sampling plan	1. N Plan ($\sqrt{N}+1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-D37.
Storage condition	Preserve in well-closed containers. Store at room temperature.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	First issue, อ้างอิง spec. ที่ทางสถาบันวิจัยฯใช้ยื่นขึ้นทะเบียน spec. No. RMS-RA-79N54180-01 Rev. No. 00 โดยสถาบันวิจัยฯ refer to ผู้ผลิต Neuland laboratories Ltd. /India	01/05/18

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Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee , 23/04/18	S. Tantitthaweewat, 24/04/18	VAREEIN , 24/04/18	Vichien Ruangwong (Acting) , 25/04/18	01/05/18
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	