

WRS
T23-2

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Glenmark
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WORKING STANDARD CERTIFICATE OF ANALYSIS

Name of Working Standard	TACROLIMUS USP		
W.S. No.	WS/159/04	A.R No	WS/16/0057
Manufacturer's Name	Concord Biotech Ltd.	Evaluated with	USPRS LOT : H0M009
Manufacturing Date	06.2016	Effective Date	07/09/2016
Expiry Date	05.2021	Valid Up To	06/09/2017

Sr. No.	TESTS	SPECIFICATION	RESULTS
1	Description	White crystals or White crystalline powder.	White crystalline powder.
2	Identification by IR :	The infrared absorption spectrum of the sample should be concordant with the spectrum obtained from Tacrolimus RS	The infrared absorption spectrum of the sample is concordant with the spectrum obtained from Tacrolimus RS
3	Organic Impurities (Procedure 2) Ascomycin 19-epimer Ascomycin Desmethyl Tacrolimus Tacrolimus 8-epimer Tacrolimus 8-Propyl analog Any individual Unspecified Impurity Total impurities	Not more than 0.1 % Not more than 0.50 % Not more than 0.1 % Not more than 0.15 % Not more than 0.15 % Not more than 0.1 % Not more than 1.0 %	Not detected Not detected Not detected Not detected 0.03 % Not detected 0.03 %
4	Water content	Not more than 4.0 %	2.18 %
5	Assay (on anhydrous basis & solvent -free basis)	Between 98.0 % and 102.0 %	99.76 %
6	Assay (as such basis)	For information	97.59%

Storage : Preserve in tight container, store at controlled room temperature.

Remarks: Above material is standardized against the reference standard (Lot: H0M009) And found to be suitable for use as working standard in routine use.

Prepared By	Checked By	Approved By
Signature	Signature	Signature
Date 06/09/2016	Date 06/09/2016	Date 07/09/2016

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