

**BILLS BIOTECH PVT. LTD.**

Plot No.-P/01, Biotech Park Phase-1, GIDC, Manjusar Industrial Estate
Village-Manjusar, Savli-Vadodara-391775

CERTIFICATE OF ANALYSIS

Product name	: TACROLIMUS USP	Spec.ref.no.	: BBL/FPS/BB/FP/03/01-02
Batch no.	: TAC21-15	STP ref.no.	: BBL/FPT/BB/FP/03/01-03
Mfg. date	: Jul-2021	A.R. no.	: BFP/21/07/003
Re-test date	: Jun-2024	Batch size	: 2.115 Kg
Storage condition	: Preserved in air-tight container up to 25°C.		

TESTS	SPECIFICATION	RESULTS
Description	White crystal or white crystalline powder.	White crystalline powder.
Solubility	Very soluble in methanol, freely soluble in N,N-dimethylformamide and in alcohol, practically insoluble in water.	Very soluble in methanol, freely soluble in N,N-dimethylformamide and in alcohol, practically insoluble in water.
Identification		
(A) By IR	The IR absorption spectrum of the sample exhibits maxima only at the same wavelength as that of a similar preparation of USP working standard.	Complies
(B) By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the assay.	Complies
Specific optical rotation (as is basis)	-110° to -115°	-111.48°
Water	NMT 4.0%	2.61 %
Residue on ignition	NMT 0.1%	0.06 %
Assay (By HPLC)	NLT 98.0% and NMT 102.0% on the anhydrous and solvent free basis	99.93%

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TESTS	SPECIFICATION	RESULTS
Organic impurities (By HPLC) (Procedure B)		
Tacrolimus open ring	For information only	ND
Tacrolimus 19-epimer	For information only	8.50%
Ascomycin 19-epimer	NMT 0.1%	ND
Ascomycin	NMT 0.5%	0.14%
Desmethyl tacrolimus	NMT 0.1%	0.03%
Tacrolimus 8- epimer	NMT 0.15%	ND
Tacrolimus 8-propyl analog	NMT 0.15%	0.09%
Any individual unspecified impurity	NMT 0.1%	0.07%
Total impurities (Excluding Tacrolimus open ring and Tacrolimus 19-epimer)	NMT 1.0%	0.37%
Residual solvents (By GC)		
Acetone	NMT 5000ppm	68.87 ppm
Di-isopropyl ether	NMT 98 ppm	4.37 ppm
Ethyl acetate	NMT 5000 ppm	Not Detected
n-Hexane	NMT 290 ppm	0.14 ppm
Toluene	NMT 890 ppm	10.80 ppm
Cyclohexane	NMT3880 ppm	1.53 ppm
Acetonitrile	NMT 410 ppm	13.97 ppm

Remarks: The product complies / ~~does not comply~~ above tests as per USP specifications.

	Prepared by (QC)	Checked by (QC)	Approved by (QC)
Sign:			
Date:	15-07-2021	15-07-2021	16-07-2021