

**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 EP	A.R. no.	:	BFP/21/07/004
Batch no.	:	TAC21-16	Batch size	:	1.500 Kg
Mfg. date	:	Jul-2021	Re-test date	:	Jun-2024
Storage condition	:	Preserved in air-tight container.			

TESTS	SPECIFICATION	RESULTS
Description	White or almost white crystalline powder.	White crystalline powder.
Solubility	Practically insoluble in water. Soluble in ethanol (96 %) Practically insoluble in heptane.	Practically insoluble in water. Soluble in ethanol (96 %) Practically insoluble in heptane.

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 EP 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
Appearance of Solution	The Solution is Clear and not more intensely coloured than reference solution GY ₇ .	Complies
Water	1.5% to 4.0%	1.99 %
Sulfated ash	Maximum 0.1%	0.06 %
Assay (By HPLC)	97.0% to 102.0% for the sum of tacrolimus, tacrolimus compound-I and tacrolimus compound -II (anhydrous substance).	99.82%

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TESTS	SPECIFICATION	RESULTS
Related substances Liquid chromatography		
Impurity A	Maximum 0.5%	0.12%
unspecified impurities	Maximum 0.15%	0.06%
Total impurities	Maximum 1.0%	0.35%
Residual solvents (By GC)		
Acetone	NMT 5000ppm	64.97 ppm
Di-isopropyl ether	NMT 98 ppm	7.03 ppm
Ethyl acetate	NMT 5000 ppm	Not Detected
n-Hexane	NMT 290 ppm	0.35 ppm
Toluene	NMT 890 ppm	6.31 ppm
Cyclohexane	NMT3880 ppm	6.87 ppm
Acetonitrile	NMT 410 ppm	40.27 ppm

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

	Prepared by (QC)	Checked by (QC)	Approved by (QC)
Sign:			
Date:	21-07-2021	21-07-2021	21-07-2021