

METAPHARMACEUTICAL

N DE LOTE:

0160275

21/05/2025



BILLS BIOTECH PVT. LTD.

Plot No.-P/01, Biotech Park Phase-1, Manjusar GIDC, Industrial Estate,
Savli, Vadodara – pin code - 391775, Gujarat, India.

CERTIFICATE OF ANALYSIS

COA No.: COA/FP/TACY24-16/016-03

Product name	TACROLIMUS MONOHYDRATE EP	Spec. Ref. No.	: BBL/FPS/BB/FP/03/09-00
Batch No.	: TACY24-16	STP Ref. No.	: BBL/FPT/BB/FP/03/09-00
Mfg. date	: Dec-2024	A.R. no.	: BFP/24/12/006
Re-test date	: Nov-2027	Batch size	: 2.045 kg
Storage condition	Preserve in airtight container. If the substance is sterile, the container is also sterile and tamper-evident.		

TESTS	SPECIFICATION	RESULTS
Appearance	White or almost white crystalline powder.	White crystalline powder.
Solubility	Practically insoluble in water, soluble in ethanol (96 %), practically insoluble in Heptane.	Complies
Identification		
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
Appearance of solution	The solution is clear and not more intensely coloured than reference solution GY ₇ .	Complies
Sulfated ash	Maximum 0.1 %	0.05 %
Water	1.5 % to 4.0 %	2.26 %
Assay (By HPLC)	97.0 % to 102.0 % on the anhydrous Substance.	99.1 %
Related substances (By HPLC)		
Impurity A	Maximum 0.5 %	0.15 %
Unspecified impurities	For each impurity Maximum 0.15%	0.07 %
Total impurities	Maximum 1.0%	0.31 %
Additional test:		
Residual solvents (By GC)		
Acetone	NMT 5000 ppm	124.52 ppm
Di-isopropyl ether	NMT 98 ppm	4.49 ppm
Ethyl acetate	NMT 5000 ppm	Not detected
n-Hexane	NMT 290 ppm	Not detected
Toluene	NMT 890 ppm	10.65 ppm
Cyclohexane	NMT3880 ppm	4.72 ppm
Acetonitrile	NMT 410 ppm	Not detected

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

Responsibility	Prepared By (QC)	Checked By (QC)	Approved By (QC)	Approved By (QA)
Sign / Date	 16-01-2025	 16-01-2025	 16-01-2025	 16-01-2025

