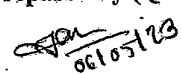
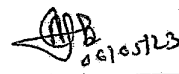
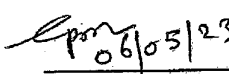


CERTIFICATE OF ANALYSIS

A WHO-GMP Certified Company

Product Name	Tacrolimus Monohydrate (EP)	Batch Number	TR23004
A.R No.	AR/FP/23-0028	Specification No.	QC/SPC/FP/0010-01
Date of Manufacturing	APR-2023	Date of Retest	MAR-2027
Batch Size	2.163 kg	Storage Condition	Store protected from moisture and at controlled temperature.

Sr. No.	Parameters	Specifications	Observation/Result
1.	Appearance	White or almost white crystalline powder	White crystalline powder
2.	Solubility	Practically insoluble in water; Soluble in ethanol 96%), Practically insoluble in heptane.	Complies
3.	Identification		
	A) By IR	The absorption maxima in the spectrum obtained with the substance under examination is concordant with Tacrolimus monohydrate reference standard/ working standard or with the reference spectrum of Tacrolimus monohydrate.	Complies
4.	Appearance of solution	The solution is clear and not more intensely coloured than reference solution GY ₇	Complies
5.	Related substances		
	Impurity A	Maximum 0.5%	0.04%
	Unspecified impurities (for each impurity)	Maximum 0.15%	Not detected
	Total impurities	Maximum 1.0%	0.16%
6.	Water Content (by KF)	1.5% to 4.0%	2.10%

Prepared by (Q.C.)  06/05/23 Sign./Date	Checked by (Q.C.)  06/05/23 Sign./Date	Approved by (Q.A.)  06/05/23 Sign./Date
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(Ref.: SOP No.: QC/036/A)



FISHFA BIOGENICS (A DIV. OF FISHFA RUBBERS LTD.)

MFG. Unit : Survey No. 43/2/2, 47/2, 50/1/2, 50/2, KUVADWA - WANKANER HIGHWAY, VILL. RAMPARA (SURYA),
TAL. RAJKOT, DIST. RAJKOT - 360 003 GUJARAT STATE, INDIA.

REG. OFFICE : Plot No. G-1357, 58, 59, 60, Lodhika GIDC Metoda-360021, Dist : Rajkot, Gujarat, INDIA.

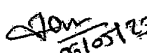
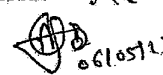
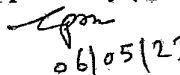
Phone: +91-2827-287579 | E-mail: marketing@fishfabioGENICS.com | web: www.fishfabioGENICS.com | CIN: U25199GJ2000PL038034

CERTIFICATE OF ANALYSIS

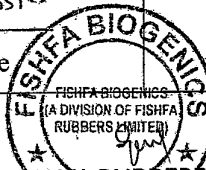
Product Name	Tacrolimus Monohydrate (EP)	Batch Number	TR23004
A.R No.	AR/FP/23-0028	Specification No.	QC/SPC/FP/0010-01
Date of Manufacturing	APR-2023	Date of Retest	MAR-2027
Batch Size	2.163 kg	Storage Condition	Store protected from moisture and at controlled temperature.

Sr. No.	Parameters	Specifications	Observation/Result
7.	Sulphated Ash	Maximum 1.0%	0.07%
8.	Assay	97.0%–102.0% on the anhydrous basis.	100.09%
9.	Residual solvents by GC (Additional test)		
	Acetone	Not more than 5000ppm	9.8 ppm
	Di-isopropyl ether	Not more than 98 ppm	7.8 ppm
	Ethyl acetate	Not more than 5000 ppm	Not detected
	n-Hexane	Not more than 290 ppm	1.2 ppm
	Toluene	Not more than 890 ppm	Not detected
	Cyclohexane	Not more than 3880 ppm	12.6 ppm
	Acetonitrile	Not more than 410 ppm	Not detected

Remarks: The material is Complies as per current EP and In-house specification

Prepared by (Q.C.)  06/05/23 Sign./Date	Checked by (Q.C.)  06/05/23 Sign./Date	Approved by (Q.A.)  06/05/23 Sign./Date
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(Ref.: SOP No.: QC/036/A)



Page 2 of 2

FISHEA BIOGENICS (A DIV. OF FISHEA RUBBERS LTD.)

MFG. Unit : Survey No. 43/2/2, 47/2, 50/1/2, 50/2, KUVADWA - WANIYANER HIGHWAY, VILL. RAMPARA (SURYA), TAL. RAJKOT, DIST. RAJKOT - 360 003 GUJARAT STATE, INDIA.

REG. OFFICE : Plot No. G-1357, 58, 59, 60, Lodhika GIDC Metoda-360021, Dist : Rajkot, Gujarat, INDIA.

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