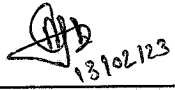
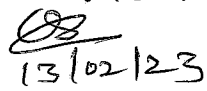
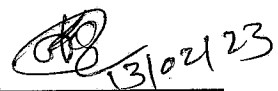


CERTIFICATE OF ANALYSIS

Product Name	Tacrolimus (IP)	Batch Number	TR23001
A.R No.	AR/FP/23-0008	Specification No.	QC/SPC/FP/0001-00
Date of Manufacturing	FEB-2023	Date of Retest	JAN-2027
Batch Size	1.668 kg	Storage Condition	Preserve in tight containers. Store at controlled room temperature.

Sr. No.	Parameters	Specifications	Observation/Result
1.	Description	White Crystals or white crystalline powder.	White crystalline powder
2.	Solubility	Soluble in methanol, ethanol and ethyl acetate, Sparingly soluble in hexane. Insoluble in water.	Complies
3.	<u>Identification</u>		
	A) By IR	The absorption maxima in the spectrum obtained with the substance under examination is concordant with Tacrolimus reference standard/ working standard.	Complies
	B) By HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the Standard solution.	Complies
4.	Sulphated ash	Not more than 0.1%	0.03%
5.	<u>Related substances (Procedure-2)</u>		
	Ascomycin 19-epimer	Not more than 0.1%	Not detected
	Ascomycin	Not more than 0.5%	0.20%
	Desmethyl tacrolimus	Not more than 0.1%	0.03%
	Tacrolimus 8- epimer	Not more than 0.15%	0.08%
	Tacrolimus 8-propyl analog	Not more than 0.15%	0.06%
	Any individual unspecified impurity	Not more than 0.1%	0.02%

Prepared by (Q.C.)  <hr/> Sign./Date	Checked by (Q.C.)  <hr/> Sign./Date	Approved by (Q.A)  <hr/> Sign./Date
--	---	---

(Ref.: SOP No.: QC/036/A)

Page 1 of 2

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.

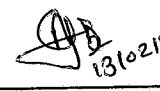
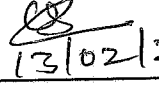
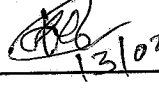
Phone: +91-2827-287579 | **E-mail:** marketing@fishfabiogenics.com | **web:** www.fishfabiogenics.com | **CIN:** U25199GJ2000PL038034

CERTIFICATE OF ANALYSIS

Product Name	Tacrolimus (IP)	Batch Number	TR23001
A.R No.	AR/FP/23-0008	Specification No.	QC/SPC/FP/0001-00
Date of Manufacturing	FEB-2023	Date of Retest	JAN-2027
Batch Size	1.668 kg	Storage Condition	Preserve in tight containers. Store at controlled room temperature.

Sr. No.	Parameters	Specifications	Observation/Result
	Total impurities	Not more than 1.0%	0.39%
6.	Specific optical rotation	-110.0 to -115.0° on the as is basis	-111.078°
7.	Water (by KF)	Not more than 4.0%	2.13%
8.	Heavy metals	Not more than 10 ppm	Less than 10 ppm
9.	Assay by HPLC	NLT 98.0% and NMT 102.0% on anhydrous and solvent free basis	100.76%
10.	Additional test: Residual solvents		
	Acetone	Not more than 5000ppm	10.37 ppm
	Acetonitrile	Not more than 410ppm	Not detected
	Ethyl acetate	Not more than 5000ppm	Not detected
	Diisopropylether	Not more than 98ppm	3.39 ppm
	n-hexane	Not more than 290ppm	Not detected
	Cyclohexane	Not more than 3880ppm	5.17 ppm
	Toluene	Not more than 890ppm	Not detected

Remarks: The material Complies above tests as per IP specification and In-house specification

Prepared by (Q.C.)  <u>13/02/23</u> Sign./Date	Checked by (Q.C.)  <u>13/02/23</u> Sign./Date	Approved by (Q.A)  <u>13/02/23</u> Sign./Date
---	--	--

(Ref.: SOP No.: QC/036/A)

Page 2 of 2

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