

CERTIFICATE OF ANALYSIS

Product : **TACROLIMUS MONOHYDRATE Ph.Eur.**
Batch No.: **P/TAC/21/01/001**

Date of Mfg.: **JANUARY 2021**
Retest Date.: **DECEMBER 2023**

S. No.	Test	Result	Specification
1.	Appearance	A white crystalline powder	White or almost white, crystalline powder.
2.	Solubility	Complies	Very soluble in Ethanol(96%), practically insoluble in water and Heptane.
3.	Identification By IR *	Complies	The Infrared absorption spectrum of the sample should be concordant with the spectrum obtained from Tacrolimus RS/WS.
4.	Appearance of solution	Complies	Solution is clear and not more intensely coloured than reference solution GY ₇
5.	Water	2.77% w/w	1.5 to 4.0% w/w
6.	Sulfated Ash	0.05% w/w	Maximum 0.1% w/w
7.	Related Substance (By HPLC): Impurity-B (Ascomycin 19- epimer) Impurity-A (Ascomycin) Impurity-C (Desmethyl Tacrolimus) Impurity-D (Tacrolimus 8-epimer) Impurity-E (Tacrolimus8-propylanalog) Impurity-H (Unspecified impurity-i) Impurity-I (Unspecified impurity-ii) Total impurities	ND 0.35% BDL 0.07% BDL 0.08% BDL 0.50%	Maximum 0.15% w/w Maximum 0.50% w/w Maximum 0.15% w/w Maximum 0.15% w/w Maximum 0.15% w/w Maximum 0.15% w/w Maximum 0.15% w/w Maximum 1.00% w/w
8.	Assay (By HPLC): The Sum of Tacrolimus, Tacrolimus compound I and Tacrolimus Compound II (anhydrous Substance)	99.27%	97% to 102% w/w

S. No.	Test	Result	Specification
9.	Residual solvents (by GC):		
	Acetone	ND	NMT 1000 ppm
	Di-Isopropyl Ether	76	NMT 100 ppm
	Ethyl Acetate	ND	NMT 2000 ppm
	Acetonitrile	ND	NMT 400 ppm
	Toluene	ND	NMT 250 ppm
	Hexane	ND	NMT 250 ppm
10.	Microbial Tests:		
	Total aerobic microbial count	10 cfu/gm	NMT 100 cfu/gm
	Total yeast and mould count	Absent	NMT 10 cfu/gm
	Specified organisms (Pathogens) (E. coli, salmonella sps., S. aureus, Pseudomonas aeruginosa)	Absent	Should be absent

*Tests carried out by the outside external laboratory.

Note: - BDL: Below disregard limit, ND: Not detected.

Storage condition: Store in an airtight container. Store at controlled room temperature.

Remarks: The above material [✓]Complies / ~~Not Complies~~ as per Ph. Eur.+IH Specification.

Prepared by

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