

10/02/2023

CERTIFICATE OF ANALYSIS

Product : TACROLIMUS MONOHYDRATE Ph. Eur.
Batch No.: P/TAC/22/12/029

Date of Mfg.: DECEMBER 2022
Retest Date.: NOVEMBER 2025

S. No.	Test	Result	Specification
1.	Appearance	White crystalline powder	White or almost white crystalline powder.
2.	Solubility	Complies	practically insoluble in water, Soluble in ethanol(96 per cent), practically insoluble in 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	2.87% 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-propylanalogue) Impurity-H (Unspecified impurity-i) Impurity-I (Unspecified impurity-ii) Total impurities	ND 0.39% BDL BDL BDL 0.07% BDL 0.46%	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)	99.37%	97% to 102% w/w

S. No.	Test	Result	Specification
9.	Residual solvents (by GC):		
	Acetone	ND	Not more than 1000ppm
	Di-Isopropyl Ether	46	Not more than 100ppm
	Ethyl Acetate	ND	Not more than 2000ppm
	Acetonitrile	ND	Not more than 400ppm
	Toluene	ND	Not more than 250ppm
	Hexane	ND	Not more than 250ppm
10.	Microbial Tests:		
	Total aerobic microbial count	10 cfu/gm	NMT 1000cfu/gm
	Total yeast and mould count	Absent	NMT 100cfu/gm
	Specified organisms		
	Escherichia coli	Absent	Should be absent/gm
	Staphylococcus aureus	Absent	Should be absent/gm
	Pseudomonas aeruginosa	Absent	Should be absent/gm
	Clostridium sporogenes	Absent	Should be absent/gm
	Candida albicans	Absent	Should be absent/gm
	Bile-Tolerant Gram-Negative bacteria (Enterobacter)	Absent	Should be absent/gm
	Salmonella species	Absent	Should be absent/10gm

*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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 Date : 18-01-2023

Checked by

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