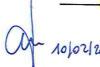


METAPHARMACEUTICAL

N DE LOTE:





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	White or almost white crystalline		
	11ppourumet	powder	powder.		
2.	Solubility	Complies	practically insoluble in water, Soluble in ethanol(96 per cent), practically		
2.	Solubliney	Compiles	insoluble in heptane.		
3.	Identification				
	D ID *	Complies	The Infrared absorption spectrum of the sample should be concordant with the spectrum obtained from		
	By IR *				
			Tacrolimus RS/WS.		
			Solution is clear and not more		
4.	Appearance of solution	Complies	intensely coloured than reference		
	Appearance of Solution		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)	ND	Maximum 0.15% w/w		
	Impurity-A (Ascomycin)	0.39%	Maximum 0.50% w/w		
	Impurity-C (Desmethyl Tacrolimus)	BDL	Maximum 0.15% w/w Maximum 0.15% w/w		
	Impurity-D (Tacrolimus 8-epimer)	BDL			
	Impurity-E (Tacrolimus8-propylanalog)	BDL	Maximum 0.15% w/w		
	Impurity-H (Unspecified impurity-i)	0.07%	Maximum 0.15% w/w		
	Impurity-I (Unspecified impurity-ii)	BDL	Maximum 0.15% w/w		
	Total impurities	0.46%	Maximum 1.00% w/w		
8.					
	The Sum of Tacrolimus, Tacrolimus compound I and				
	Tacrolimus Compound II	99.37%	97% to 102% w/w		
	(anhydrous Substance)				

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		Set .	
	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		Checked by		Approved by	
Name	: R. Shini, Vasarao	Name	: E-Harri barbu	Name	: R. HANUMANTHA RAS
Designation	: Tr-officer-ac	Designation	: Sr-officer-Q-c	Designation	: MANAGER-OUALETY
Signature	: R3	Signature	: ED	Signature	: 42
Date	: 18.01.2023	Date	: 18-01-2023	Date	: 18/01/2023