

CONCORD BIOTECH LIMITED

Unit - 1, 1482-1486, Trasad Road, Dholka, Dist. Ahmedabad-382225. (India)
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CERTIFICATE OF ANALYSIS

19/05/2024

Product	TACROLIMUS MONOHYDRATE Ph.Eur.	A. R. No.	CBL-0403A524080A
Batch No.	0403A524080	Mfg. Date	Mar 2024
Batch size	1.760 Kg	Retest Date	Feb 2027
S.N.	Tests	Specifications	Observations
1	Appearance	White or almost white crystalline powder	White crystalline powder
2	Solubility	Practically insoluble in water, soluble in ethanol (96%) and practically insoluble in heptane	Practically insoluble in water, soluble in ethanol (96%) and practically insoluble in heptane
3	Identification by IR	The IR absorption spectrum of the preparation of the sample exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding EP reference standard/ working standard.	The Infrared absorption spectrum of the preparation of the sample exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding working standard.
4	Appearance of solution	The solution is clear and not more intensely coloured than reference solution GY ₇ .	The solution is clear and not more intensely coloured than reference solution GY ₇ .
5	Related substance (by HPLC)		
	Ascomycin (Impurity A)	Maximum 0.5 %	Below disregard limit
	Any individual unspecified impurity	Maximum 0.10 %	0.07 %
	Total impurities (excluding Tacrolimus compound I and Tacrolimus compound II)	Maximum 1.0 %	0.07 %
6	Water (by KF)	1.5 % to 4.0%	2.1 %
7	Sulphated Ash	Maximum 0.1 %	0.03 %
8	Assay (By HPLC)	97.0 % to 102.0 % for the sum of Tacrolimus, Tacrolimus compound I and Tacrolimus compound II on the anhydrous substance basis	99.8 %
Additional Tests			
9	Residual solvents (By GC Headspace)		
	Acetone	NMT 1000 ppm	Below detection limit
	Di isopropyl ether	NMT 600 ppm	Below detection limit
	Ethyl acetate	NMT 2000 ppm	Below detection limit
	Acetonitrile	NMT 400 ppm	Below detection limit
	Toluene	NMT 250 ppm	Below detection limit
	Hexane	NMT 250 ppm	Below detection limit
10	Particle size distribution	For information	d (0.1): 4 µm d (0.5): 14 µm d (0.9): 59 µm
11	Microbial tests:		
	Total viable aerobic count	NMT 1000 cfu/g	Less than 10 cfu/g
	Total mold and yeast count	NMT 100 cfu/g	Less than 10 cfu/g
	Test for specified microorganism		
	E. coli	Should be absent/g	Absent/g
	S. aureus	Should be absent/g	Absent/g
	Pseudomonas aeruginosa	Should be absent/g	Absent/g
	Candida albicans	Should be absent/g	Absent/g
	Clostridium sporogenes	Should be absent/g	Absent/g
	Bile tolerant gram - negative bacteria	Should be absent/g	Absent/g
	Salmonella spp	Should be absent/10g	Absent/10g

Storage: Store in airtight container up to 25°C.

Remarks: The material complies as per Ph. Eur. and in-house specification no STP/QC/FP/127-00.

Date of Report: Apr 08, 2024

Compiled By (QC)

(K. K. Vakil- Manager) 1ck
08/04/2024

Date:

Checked By (QC)

(S. K. Jha- Sr. GM)
08/04/2024

Date:

Approved By (QA)

(Uday Naik- Sr. GM)
09/04/2024

Date:

Registered Office : 1482-1486, Trasad Road, Dholka, Dist. Ahmedabad-382225. (India) CIN No.: U24230GJ1984PLC007440

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Batch Information

Batch No	0403A524080	Mfg Date	Mar 2024
Product Name	Tacrolimus Monohydrate Ph.Eur.	Retest Date	Feb 2027
GTIN Number	8906164900199	Batch Size	1.760 Kg

Container Details

Sr No	Batch Unique ID	Date & Time	SSCC Code	Gross Weight	Tare Weight	Net Weight	Container No	User Details
1	20240410012	10-04-2024 09:59:45	(00)089061649000146323	0.360 Kg	0.260 Kg	0.100 Kg	1 of 1	3818, OPERATOR

Manufactured By:

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