

CONCORD BIOTECH LIMITED

Unit - 1, 1482-1486, Trasad Road, Dholka, Dist. Ahmedabad-382225. (India)
Phones : +91-2714-222604, 608666 Fax : +91-2714-222504

CERTIFICATE OF ANALYSIS

Product	TACROLIMUS MONOHYDRATE Ph.Eur.	A. R. No.	CBL-0403522098A
Batch No.	0403522098	Mfg. Date	Apr 2022
Batch size	1840 g	Retest Date	Mar 2025
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 ₃ .	The solution is clear and not more intensely coloured than reference solution GY ₃ .
5	Related substance (by HPLC)		
	Ascomycin (Impurity A)	Maximum 0.5 %	Below disregard limit
	Any individual unspecified impurity	Maximum 0.10 %	Below disregard limit
	Total impurities (excluding Tacrolimus compound I and Tacrolimus compound II)	Maximum 1.0 %	Nil
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	99.4 %
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): 20 µm d(0.9): 82 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 20, 2022

Compiled By (QC)

(K. K. Vakil- Manager)

Date:

Checked By (QC)

(S. K. Jha- Sr. GM)

Date:

Approved By (QA)

(T. K. Saha- GM)

Date:

TACROLIMUS MONOHYDRATE Ph.Eur.
(Non-Sterile Bulk)

CAS No. : [109581-93-3]	Batch No. : 0403522098
Mfg. Lic. No. : G/1641	Mfg. Date : Apr 2022
Container No. : 03 of 08	Retest Date : Mar 2025
	Gross Wt. : 408.2 gm
	Tare Wt. : 258.2 gm
	Net Wt. : 150.0 gm

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

Manufactured by
CONCORD BIOTECH LIMITED
1482-1486, TRASAD ROAD, DHOLKA,
DISTRICT - AHMEDABAD
PIN CODE - 382225, INDIA

Master Label No.: L-03-16-00