

CONCORD BIOTECH LIMITED

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CERTIFICATE OF ANALYSIS

Director Técnico

Product	TACROLIMUS (A5 MONOHYDRATE)	A. R. No.	CBL-03515060
Batch No.	03515060	Mfg. Date	May 2015
Batch size	1640 g	Retest Date	Apr 2018

S.N.	Tests	Specification	Observation.
1	Description	White to off white powder	White powder
2	Solubility	Soluble in acetone, chloroform and ethyl acetate. Insoluble in water.	Soluble in acetone, chloroform and ethyl acetate. Insoluble in water.
3	Identification (a) By IR (b) By HPLC	The Infrared spectrum of the test sample in KBr must be concordant with that of a similar preparation of Tacrolimus Monohydrate reference / working standard. The retention time of the major peak in the chromatogram of sample corresponds to the standard as obtained under assay test.	The Infrared spectrum of the test sample is concordant with Tacrolimus Monohydrate working standard. Standard RT : 24.8 min Sample RT : 24.8 min
4	Water (by KF)	NMT 3.0 % w/w	2.0 %
5	Specific Rotation (1.0 % solution in chloroform, on anhydrous basis)	Between -80° and -90°	-83°
6	Melting Range	Between 123° and 130°C	123°C - 126°C
7	Heavy Metals	NMT 0.002 %	Less than 0.002 %
8	Residue on Ignition	NMT 0.20 % w/w	0.04 %
9	Chromatographic purity % (By HPLC)		
	1. Impurity A [Ascmycin] 2. Impurity B [Dihydro Tacrolimus] 3. Impurity D [Delta Lactone] 4. Any individual unknown impurity 5. Total impurities [Excluding Tautomers]	NMT 0.15 % NMT 0.15 % NMT 0.15 % NMT 0.10 % NMT 1.0 %	Not detected Not detected Below disregard limit 0.07 % 0.21 %
10	Content of Tautomers (By HPLC) [Imp.C]		
	Tautomer I Tautomer II Tautomers I+II	Report value Report value NMT 1.0 %	0.22 % 0.32 % 0.54 %
11	Assay (By HPLC) [% w/w on anhydrous basis] (Excluding Tautomers)	98.0 % to 102.0 %	99.1 %
Additional Tests			
12	Residual Solvents (By GC Headspace)		
	Acetone Di isopropyl Ether Ethyl acetate Acetonitrile Toluene Hexane	NMT 1000 ppm NMT 600 ppm NMT 2000 ppm NMT 400 ppm NMT 250 ppm NMT 250 ppm	Below detection limit Below detection limit Below detection limit Below detection limit Below detection limit Below detection limit
13	Particle Size Distribution	As per customer requirement	d(0.9): 78 microns
14	Microbial Tests		
	Total Viable aerobic count Total mold and yeast count Test for specified microorganism [E. coli, Salmonella spp., S. aureus, Pseudomonas aeruginosa]	NMT 1000 cfu / g NMT 100 cfu / g Should be absent / g	Less than 10 cfu / g Less than 10 cfu / g Absent / g

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

Remarks: The material complies as per in house specification no. SPC/QC/FP/003-08.

Date of Report: May 12, 2015

Compiled By (QC)

Date:

(Dipak Patel-Sr.AM)

Checked By (QC)

Date:

(S.K. Jha-GM)

Approved By (QA)

Date:

(Tapas Saha-DGM)