Lot: 009/2/15

CONCORD BIOTECH LIMITED

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CERTIFICATE OF ANALYSIS

Product	CICLOSPORIN Ph.Eur.	A.R.No.	CBL- 13415078A
Batch No.	13415078	Mfg. Date	Oct 2015
Batch size	15.100 Kg	Retest Date	Sep 2019

S.N.	Tests	Specification	Observation
1	Description	White or almost white powder.	White powder.
2	Solubility	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride.	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride.
3	Identification A. [By IR]	The absorption maxima in the spectrum obtained with the substance to be examined corresponds in position and relative size to those in the spectrum obtained with ciclosporin reference standard / working standard.	The absorption maxima in the spectrum obtained with the substance corresponds in position and relative size to those in the spectrum obtained with ciclosporin working reference standard.
	B. [By HPLC]	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a) prepared under the assay test.	Std RT: 28.2 minutes Test RT: 28.3 minutes
4	Appearance of Solution	The solution is clear and not more intensely colored than reference solution Y_5, BY_5 or R_7.	The solution is clear. Complies
5	Specific Rotation (Calculated with reference to the dried substance)	Between -185° and -193°	-187°
6	Loss on Drying	Not more than 2.0 %	0.46 %
7	Heavy Metals	Maximum 20 ppm	Less than 20 ppm
8	Related substances [By HPLC]		
	(a) Ciclosporin C	Not more than 0.7 %	0.08 %
	(b) Ciclosporin B	Not more than 0.7 %	Below disregard limit
	(c) Ciclosporin L	Not more than 0.7 %	Below disregard limit
	(d) Ciclosporin U	Not more than 0.7 %	0.11 %
	(e) Ciclosporin H	Not more than 0.7 %	Not detected
	(f) Dihydro Ciclosporin A	Not more than 0.7 %	0.31 %
	(g) Ciclosporin G	Not more than 0.7 %	0.30 %
	(h) Ciclosporin D	Not more than 0.7 %	0.23 %
	(i) Ciclosporin E	Not more than 0.7 %	Not detected
	(j) Isociclosporin A	Not more than 0.7 %	Below disregard limit
	(k) Any individual unknown impurity	Not more than 0.10 %	Below disregard limit
	(l) Sum of all impurities	Not more than 1.5 %	1.0 %
9	Assay [By HPLC] (on the dried basis)	98.5% to 102.0% ($C_{62}H_{111}N_{11}O_{12}$).	99.3 %
Additional Tests :			
10	Residual solvents (By GC HEADSPACE)		
	Acetone	NMT 4500 ppm	Below disregard limit
	Ethyl acetate	NMT 2000 ppm	Below disregard limit
11	Particle size distribution	For information only	d(0.9) : 77 microns
12	Microbial EnumerationTests:		
	Total viable aerobic count	NMT 1000 CFU / g	20 cfu / g
	Total mold and yeast count	NMT 100 CFU / g	Less than 10 cfu / g
	Test for specified microorganism [E. coli, Salmonella spp.,S. aureus, Pseudomonas acruginosa, Candida albicans, Clostridium sporogenes]	Should be Absent / g	Absent / g

Storage : Store in an airtight container, protected from light upto 25°C.
Remarks: The material complies as per Ph.Eur and in house specification no. STP/QC/FP/033-02.
Date of Report: Nov 10, 2015.

Compiled By (QC)
Date: 10/11/2015
(Jignesh Gandhi- AM)

Checked By (QC)
Date: 10/11/2015
(S. K. Jha-GM)

Approved By (QA)
Date: 11/11/2015
(Tapas Saha-DGM)

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