Lot. 9020218

CONCORD BIOTECH LIMITED

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CERTIFICATE OF ANALYSIS

Product	**CICLOSPORIN Ph.Eur.**	**A.R.No.**	**CBL- 13417083**
Batch No.	**13417083**	**Mfg. Date**	**Nov. 2017**
Batch size	**31.415 Kg**	**Retest Date**	**Oct 2021**

S.N.	Tests	Specifications	Observations
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] B. [By HPLC]	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 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.	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 standard. Std RT: 28.3 minutes Test RT: 28.4 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 optical rotation (Calculated with reference to the dried substance)	Between -193° and -185°	-189°
6	Loss on Drying	Not more than 2.0 %	0.58 %
7	Heavy Metals	Maximum 20 ppm	Less than 20 ppm
8	Related substances [By HPLC]		
	(a) Ciclosporin C (b) Ciclosporin B (c) Ciclosporin L (d) Ciclosporin U (e) Ciclosporin H (f) Dihydrociclosporin A (g) Ciclosporin G (h) Ciclosporin D (i) Ciclosporin E (j) Isociclosporin A (k) Any individual unknown impurity (l) Sum of all impurities	Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.7 % Not more than 0.10 % Not more than 1.5 %	0.11% Below disregard limit Below disregard limit 0.09% Not detected 0.28% 0.19% 0.14% Not detected Below disregard limit. Below disregard limit 0.81%
9	Assay [By HPLC] (on the dried basis)	98.5% to 102.0% (as $C_{62}H_{111}N_{11}O_{12}$).	100.2 %
Additional Tests :			
10	Residual solvents (By GC HEADSPACE)		
	Acetone Ethyl acetate	NMT 4500 ppm NMT 2000 ppm	502 ppm Below detection limit
11	Particle size distribution	For information only	d(0.9) : 44 microns
12	Microbial EnumerationTests:		
	Total viable aerobic count Total mold and yeast count Test for specified microorganism [E. coli, Salmonella spp.,S. aureus, Pseudomonas aeruginosa, Candida albicans, Clostridium sporogenes]	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 an airtight container, protected from light upto 25°C.
Remarks: The material complies as per Ph. Eur and in-house specification no. SPC/QC/FP/033-02.
Date of Report: Dec 25, 2017.

Compiled By (QC)
(D.N.Panchal-Sr. AM)
Date: 25/12/2017

Checked By (QC)
(S.K.Jha -GM)
Date: 25/12/2017

Approved By (QA)
(Tapas Saha-DGM)
Date: 27/12/2017