

Lot: 0101219

CONCORD BIOTECH LIMITED

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CERTIFICATE OF ANALYSIS

Product	CICLOSPORIN Ph.Eur.	A.R.No.	CBL- 13419088
Batch No.	13419088	Mfg. Date	Nov 2019
Batch size	30.100Kg	Retest Date	Oct 2023

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, BY, or R.	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 %	0.40 %
7	Related substances [By HPLC]		
	(a) Ciclosporin C	Not more than 0.7 %	Below disregard limit
	(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 %	Below disregard limit
	(e) Ciclosporin H	Not more than 0.7 %	Not detected
	(f) Dihydrociclosporin A	Not more than 0.7 %	0.29 %
	(g) Ciclosporin G	Not more than 0.7 %	0.19 %
	(h) Ciclosporin D	Not more than 0.7 %	0.30 %
	(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 %	0.78 %
8	Assay [By HPLC] (on the dried basis)	98.5% to 102.0% (as C ₃₇ H ₆₁ N ₁₁ O ₁₂).	99.6 %

Additional Tests :

9.	Residual solvents (By GC HEADSPACE)		
	Acetone	NMT 4500 ppm	Below quantitation limit
	Ethyl acetate	NMT 2000 ppm	22 ppm
10	Particle size distribution	For information only	d(0.9) : 50 microns
11	Microbial Enumeration 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
	Salmonella spp.	Should be Absent / 10 g	Absent / 10g

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/033-03.

Date of Report: Nov 27, 2019

Compiled By (QC)

(B.H.Patel-Executive)

Date:

Checked By (QC)

(S.K.Jha-Sr.GM)

Date:

Approved By (QA)

(T.K.Saha-GM)

Date: