

CONCORD BIOTECH LIMITED

Regd. Office & Plant : 1482-1486, Trasad Road, Dholka, Dist. Ahmedabad-382225. (India)
 Phones : +91-2714-221904, 398200 Fax : +91-2714-222504 Website : www.concordbiotech.com

CERTIFICATE OF ANALYSIS

Product	CICLOSPORIN Ph.Eur.	A.R.No.	CBL- 13414061A
Batch No.	13414061	Mfg. Date	Aug 2014
Batch size	17.100 Kg	Retest Date	Jul 2018
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] 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 reference standard. Std RT: 27.3 min Test RT: 27.5 min
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 %	0.53 %
7	Heavy Metals	Maximum 20 ppm	Less than 20 ppm
8	Related Compounds [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 %	0.16 %
	(e) Ciclosporin H	Not more than 0.7 %	0.07 %
	(f) Dihydro Ciclosporin A	Not more than 0.7 %	0.30 %
	(g) Ciclosporin G	Not more than 0.7 %	0.23 %
	(h) Ciclosporin D	Not more than 0.7 %	0.14 %
	(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 %	0.90 %
9	Assay [By HPLC] (on the dried basis)	98.5% to 102.0% (C ₂₂ H ₃₃ N ₁₁ O ₈).	98.9 %
Additional Tests :			
10	Residual solvents (By GC HEADSPACE)		
	Acetone	NMT 4500 ppm	61 ppm
	Ethyl acetate	NMT 2000 ppm	Below detection limit
11	Particle size distribution	For information only	d(0.9) : 62 microns
12	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, Salmonella spp., S. aureus, Pseudomonas aeruginosa, 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/033-01.

Date of Report: Aug 28, 2014.

Compiled By (QC) *Dipak Patel*
 Date: *28/08/2014*
 (Dipak Patel- Sr.AM)

Checked By (QC)
 Date: *29/08/2014*
 (S.K. Jha-GM)

Approved By (QA)
 Date: *29/08/2014*
 (Tapas Saha-DGM)

FAGRON IBÉRICA, S.A.U
 Corresponde al lote de Fagron:

14L 30-B01