

CONCORD BIOTECH LIMITED

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CERTIFICATE OF ANALYSIS

Product	Mycophenolate Mofetil Ph. Eur.	A. R. No.	CBL-0507C623110
Batch No.	0507C623110	Mfg. Date	Jun 2023
Batch Size	147.980 Kg	Retest Date	May 2026

S.N.	Tests	Specifications	Observations
1	Appearance	White or almost white, crystalline powder.	Almost white crystalline powder.
2	Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in anhydrous ethanol.	Practically insoluble in water, freely soluble in acetone, sparingly soluble in anhydrous ethanol.
3	Identification		
	a. By Infrared absorption	Infrared spectrum of test sample should be concordant with the reference/working standard of Mycophenolate Mofetil.	Infrared spectrum of test sample is concordant with the working standard of Mycophenolate Mofetil.
	b. Melting Point	About 96°C	96°C
4	Appearance of the solution (1% w/v solution in 96% ethanol)	The solution should be clear and colorless	The solution is clear and colorless.
5	Related substances (By HPLC)		
	Impurity F (RRT about 0.3)	NMT 0.5%	0.10 %
	Impurity A (RRT about 0.4)	NMT 0.1%	Below disregard limit
	Impurity H (RRT about 0.5)	NMT 0.1%	Not detected
	Impurity G (RRT about 0.6)	NMT 0.1%	Not detected
	Impurity B (RRT about 0.8)	NMT 0.2%	Below disregard limit
	Impurity D (RRT about 1.2)	NMT 0.1%	Not detected
	Impurity E (RRT about 1.6)	NMT 0.1%	Below disregard limit
	Any other impurity	NMT 0.1%	Below disregard limit
	Total impurities	NMT 0.7%	0.10 %
6	Loss on Drying	NMT 0.5 %	0.15 %
7	Sulphated Ash	NMT 0.1 %	0.03 %
8	Assay (On dried Basis)	98.0 - 102.0 %	99.5 %
Additional Tests			
9	Residual Solvents (By GC HEADSPACE)		
	Isobutyl acetate	NMT 2000 ppm	390 ppm
	Xylene	NMT 300 ppm	13 ppm
	Cyclohexane	NMT 1000 ppm	Below detection limit
	Acetone	NMT 1000 ppm	114 ppm
	Acetonitrile	NMT 400 ppm	Below detection limit
	Toluene	NMT 300 ppm	Below quantitation limit
10	Particle Size distribution	For information only	d (0.1): 1 microns d (0.5): 8 microns d (0.9): 22 microns
11	Microbial tests		
	Total viable aerobic count	NMT 100 cfu/g	Less than 10 cfu/g
	Total mold and yeast count	NMT 10 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
	Bile tolerant gram - negative bacteria	Should be absent/g	Absent/g
	Salmonella spp.	Should be absent/10g	Absent/10g

Storage: Preserve in closed containers protected from light.

Remark: The material complies as per Ph. Eur. and In-house specification no. SPC/QC/FP/014-06.

Date of Report: Jun 16, 2023

Compiled By (QC)

(K. K. Vakil - Manager)

Date:

Checked By (QC)

(S. K. Jha- Sr. GM)

Date:

Approved By (QA)

(T. K. Saha- GM)

Date:

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