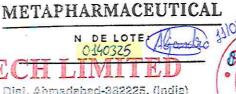
METAPHARMACEUTICAL

N DE LOTE:







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CERTIFICATE OF ANALYSIS

Product	Mycophenolate Mofetil Ph. Eur.	A. R. No.	CBL-0507C625004
Batch No.	0507C625004	Mfg. Date	Jan 2025
Batch Size	147.760 Kg	Retest Date	Dec 2027

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		1-1		
	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 i concordant with the workin 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) Impurity A (RRT about 0.4) Impurity H (RRT about 0.5) Impurity G (RRT about 0.6) Impurity B (RRT about 0.8) Impurity D (RRT about 1.2) Impurity E (RRT about 1.6) Any other impurity Total impurities	NMT 0.5% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.2% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1%	0.06 % Below disregard limit Not detected Below disregard limit Below disregard limit Not detected Not detected Below disregard limit 0.06 %		
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 %	99.9 %		
Additi	onal Tests	A.J.			
9	Residual Solvents (By GC HEADSPACE)				
10	Isobutyl acetate Xylene Cyclohexane Acetone Acetonitrile Toluene Particle Size distribution	NMT 2000 ppm NMT 300 ppm NMT 1000 ppm NMT 1000 ppm NMT 400 ppm NMT 300 ppm For information only	385 ppm Below quantitation limit Below detection limit 17 ppm Below detection limit Below detection limit d (0.1): 1 microns d (0.5): 7 microns		
			d (0.9): 20 microns		
11	Microbial limit tests:				
	Total viable aerobic count Total mould and yeast count	NMT 100 cft/g NMT 10 cft/g	Less than 10 cfu/g Less than 10 cfu/g		
	Test for specified microorganism				
	E. coli S. aureus	Should be absent/g Should be absent/g Should be absent/g	Absent/g Absent/g Absent/g		
	Pseudomonas aeruginosa Candida albicans Clostridium sporogenes Bile tolerant gram - negative bacteria	Should be absent/g Should be absent/g Should be absent/g	Absent/g Absent/g Absent/g		

Remark: The material complies as per Ph. Eur. and In-house specification no. STP/QC/FP/014-07.

Date of Report: Jan 17, 2025

Compiled By (QC) (K. K. Vakil-Manager) 1019.075

Checked By (QC)

(S. K. Jha- Sr. GM)

Date:

Approved By (QA) (Dhaval Rana- Sr. Manager)

Date:

18/01/20