

METAPHARMACEUTICAL

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Emcure

F&A PHARMA

07/06/2023



COPY-1

CERTIFICATE OF ANALYSIS

Name of Material	Mycophenolate Mofetil Ph.Eur.		
Manufactured by	Emcure Pharmaceuticals Limited		
A.R. No.	40000863111	Release Date	03.MAY.2023
Batch No.	10MN123034	Quantity	195.390 KG
Mfg. Date	26.MAR.2023	Retest Date	25.MAR.2028
		Page	1 of 4

Sr. No.	Tests	Specification	Results
1	Appearance	White or almost white, crystalline powder. It melts about 96°C.	White crystalline powder. It melts at 96°C.
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 spectrophotometry	The infrared absorption spectrum of the Sample preparation should exhibit maxima at the same wavenumbers as that of similar preparation of corresponding standard.	Meets the requirement.
	B) By HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay by HPLC.	Meets the requirement.
4	Appearance of solution	The solution should be clear and colourless.	Meets the requirement.
5	Related substances by HPLC		
	Impurity A	Not more than 0.1%	Below disregard limit.
	Impurity B	Not more than 0.2%	Below disregard limit.
	Impurity D	Not more than 0.1%	Not detected.

Prepared by : Kiran Phule	Approved by : Navneet Dwivedi
Date : 02.05.2023	Date : 03.05.2023
QC Personnel : ASST. MANAGER	Head QA/Designee : MANAGER

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Emcure Pharmaceuticals Limited

D - 24 & D - 24/1, M.I.D.C., Kurkumbh, Tal.Daund, Dist. Pune - 413 802

Phone Nos. : 02117 - 235742 / 350000 Telefax No. : 02117 - 235743

Registered Office : Emcure House, T-184, M.I.D.C., Bhosari, Pune 411 026. INDIA

Phone Nos. : +91 20 35010000, 40700000 Fax No. : 91 - 20 - 35010111 E.mail : corporate@emcure.co.in

CIN : U24231PN1981PLC024251, Website : www.emcure.com

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Sr. No.	Tests	Specification	Results
	Impurity E	Not more than 0.1%	Below disregard limit.
	Impurity F	Not more than 0.5%	Below disregard limit.
	Impurity G	Not more than 0.1%	Not detected.
	Impurity H	Not more than 0.1%	Not detected.
	Any other impurity	Not more than 0.1%	Below disregard limit.
	Total impurities	Not more than 0.7%	Below disregard limit.
6	Loss on drying	Maximum 0.5% w/w	0.2%w/w
7	Sulfated ash	Maximum 0.1% w/w	0.0% w/w (0.02% w/w)
8	Assay by HPLC	Not less than 98.0% w/w and not more than 102.0% w/w, calculated on the dried basis.	100.1%w/w
9	Residual Solvents by GC-MS		
	Ethyl acetate	Not more than 5000 ppm	119ppm
	Toluene	Not more than 890 ppm	55ppm
	n-Butyl acetate	Not more than 5000 ppm	Not detected.
10	Z-Mycophenolate mofetil content by UPLC	Not more than 0.10%	Not detected.
11	Microbiological examination		
	a) Microbial Enumeration Tests		
	i) Total aerobic microbial count	Not more than 10^3 cfu/g	<10cfu/gm
	ii) Total combined yeasts and molds count	Not more than 10^2 cfu/g	<10cfu/gm

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Sr. No.	Tests	Specification	Results
	b) Test for Specified Microorganisms:		
	Escherichia Coli	Should be absent per g	Absent/g
12	Particle size by Malvern	d(0.9): Not more than 70 µm	45µm

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Test Name	Impurity Name	LOQ (% w.r.t. sample)	LOD (% w.r.t. sample)	Disregard limit (% w.r.t. sample)
1) Related substances by HPLC	Impurity-F	--	--	0.05%
	Impurity-A	--	--	0.05%
	Impurity-H	--	--	0.05%
	Impurity-G	--	--	0.05%
	Impurity-B	--	--	0.05%
	Mycophenolate Mofetil	--	--	0.05%
	Z-Mycophenolate Mofetil	--	--	0.05%
	Impurity-D	--	--	0.05%
2) Residual Solvents by GC-HS	Impurity-E	--	--	0.05%
	Ethyl acetate	25 ppm	--	--
	Toluene	18 ppm	--	--
3) Z-Mycophenolate Mofetil content by UPLC	n-Butyl acetate	50 ppm	--	--
	Z-Mycophenolate Mofetil	0.04%	--	--

Remark : The product complies as per specification number, SC-DS-322/03

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