




### Certificate Of Analysis

Name of material	MYCOPHENOLATE MOFETIL Ph. Eur.		
Manufactured by	Emcure Pharmaceuticals Limited		
A.R. No.	40000648806	Release date	07 MAR 2019
Batch No.	5MYN119001	Quantity	84.60 KG
Mfg. date	16 JAN 2019	Expiry date	15 JAN 2024

Sr. No.	Tests	Specifications	Results
<b>CHARACTERS</b>			
01	Appearance	White or almost white, crystalline powder. It melts about 96°C.	White crystalline powder. It melts at 97°C.
02	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.

### RELEASE SPECIFICATION

Sr. No.	Tests	Specifications	Results
03	Identification :		
	A) Infrared absorption	The infrared absorption spectrum of the test preparation should exhibit maxima at the same wavelengths 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.
04	Appearance of solution	The solution should be clear and colourless.	Meets the requirement.

Compiled by : 	Checked by : 	Approved by : 
Date : 07 Mar 2019	Date : 07 Mar 2019	Date : 07 Mar 2019
Operating Personnel QC	Head QC / Designee	Head QA / Designee

### Emcure Pharmaceuticals Limited

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

Phone Nos. : 02117 - 235742 / 305000 Telefax No. : 02117 - 235743

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




Phone Nos. : + 91 20 30610000, 27120084 Fax No. : 91 - 20 - 30610111 E.mail : corporate@emcure.co.in

Corporate Identity Number (CIN) : U24231PN1981PLC024251

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05	Related substances by HPLC		
	Impurity A	Not more than 0.1%	Below disregard limit.
	Impurity B	Not more than 0.2%	Not Detected.
	Impurity D	Not more than 0.1%	Not Detected.
	Impurity E	Not more than 0.1%	Below disregard limit.
	Impurity F	Not more than 0.5%	0.1%
	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%	0.1%
06	Heavy metals	Maximum 20 ppm	Meets the requirement.
07	Loss on drying	Maximum 0.5% w/w	0.1 %w/w
08	Sulfated ash	Maximum 0.1% w/w	0.0 %w/w (0.02%w/w)
<b>Additional Tests :</b>			
09	Assay by HPLC	Not less than 98.0% w/w and not more than 102.0% w/w, calculated on the dried basis.	99.5 % w/w

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10	Residual solvents by GC-HS  Ethyl acetate  Toluene  n-Butyl acetate	Not more than 5000 ppm  Not more than 890 ppm  Not more than 5000 ppm	288 ppm  32 ppm  Not Detected.
11	Z-Mycophenolate mofetil content by UPLC	Not more than 0.10%	Not Detected.
12	Microbiological examination  a) Microbial Enumeration Tests :		
	i) Total aerobic microbial count	Not more than $10^3$ cfu/g	Less than 10 cfu/g
	ii) Total combined yeasts and molds count	Not more than $10^2$ cfu/g	Less than 10 cfu/g
	b) Test for specified microorganisms :		
	<i>Escherichia Coli</i>	Should be absent per g	Absent
13	Particle size by Malvern	d(0.9): Not more than 70 $\mu$ m	61 $\mu$ m

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1. Related substances by HPLC:

Disregard limit: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

2. Limit of quantitation (LOQ) for Z-Mycophenolate mofetil content by UPLC

a) Z-Mycophenolate mofetil = 0.04 %




3. Limit of quantitation (LOQ) for Residual solvents by GC-HS, are as below

a) Ethyl acetate = 25 ppm

b) Toluene = 18 ppm

c) *n*-Butyl acetate = 50 ppm

Remark : The product complies as per specification number SC-DS-322/01

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