Emcure



Page No.: 1 of 4

		dermonen i kan dikulukura katala kala kala da					
			Certificate Of Anal	ysis			
Name of material MYCOF			PHENOLATE MOFETIL Ph. Eur.				
Manufactured by Emcure		Emcure	e Pharmaceuticals Limited				
A.R. No. 400006		400006	Release Release		date	07 MAR 2019	
Batch No. 5MYN1		5MYN1	119001 Quantity		84.60 KG		
Mfg. date 16 JAN		16 JAN	2019 Expiry da		ate 15 JAN 2024		
Sr. Tests		4.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0	Specifications	Specifications		Results	
			CHARACTERS				
01	Appearance		White or almost white, crystalline It melts about 96°C.	powder.	. 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	ON			
Sr. No.	LACTE		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 p the Sample solution corresponds of the Standard solution, as obta the Assay by HPLC.	on corresponds to that olution, as obtained in		Meets the requirement.	
04	Appearance o solution	f	The solution should be clear and colourless.			Meets the requirement.	
					l		

~		•			
1 ' 1	٦m	nı	വവ	nı	, .
\sim	,,,,	N:	led	IJγ	

Date

9

: 01Wax 501d

Operating Personnel QC

Checked by :

Date

: 07 Marzo19

Head QC (Designee)

Approved by:

Date

Head QA /(Designee)

07 MAR 2019

Emcure Pharmaceuticals Limited

Emoure

Compiled by:

Operating Personnel QC

Date

: 02 enan 5013



Page No.: 2 of 4

Certificate Of Analysis							
Nam	ne of material	MYCOI	PHENOLATE MOFETIL Ph. Eur.	NOLATE MOFETIL Ph. Eur.			
Manufactured by Emcure			Pharmaceuticals Limited				
A.R. No. 400006		400006			date	07 MAR 2019	
Batch No. 5MYN1		5MYN1	19001	Quantity		84.60 KG	
Mfg. date 16 JAN		16 JAN	2019	Expiry d	ate	15 JAN 2024	
Sr. Tests No.			Specifications	ecifications		esults	
05	05 Related substances by HPLC			^	0	w disregard limit	
	Impurity A		Not more than 0.1%		Below disregard limit.		
**************************************	Impurity B		Not more than 0.2%		Not De	tected.	
-	Impurity D		Not more than 0.1% Not Det		tected.		
	Impurity E		Not more than 0.1%		Below	Below disregard limit.	
	Impurity F		Not more than 0.5%		0.1%	0.1%	
Impurity G			Not more than 0.1% Not Detected		etected.		
	Impurity H		Not more than 0.1%		Not Detected.		
	Any other impurity		Not more than 0.1%	Below disregard limit.		disregard limit.	
	Total Impurities		Not more than 0.7%		0.1%		
06 Heavy metals			Maximum 20 ppm		Meets the requirement.		
07	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)		
Add	Additional Tests :						
09 Assay by HPLC		.c	Not less than 98.0% w/w and than 102.0% w/w, calculated on basis.		99.5 % w/w		
				1			

Emcure Pharmaceuticals Limited

: 07 marro19

Approved by:

Head QA / Designee

Date

Checked by:

Head QC / Designee

Date

Phone Nos.: + 91 20 30610000, 27120084 Fax No.: 91 - 20 - 30610111 E.mail: corporate@emcure.co.in Corporate Identity Number (CIN): U24231PN1981PLC024251

Emcure

Compiled by:



Page No.: 3 of 4

Certificate Of Analysis							
Nam	ne of material	MYCOPHEN	NOLATE MOFETIL Ph. Eur.				
Manufactured by		Emcure Pharmaceuticals Limited					
A.R. No.		4000064880	6	Release da	ate	07 MAR 2019	
Bato	:h No.	5MYN11900	1	Quantity		84.60 KG	
Mfg.	date	16 JAN 2019		Expiry date 15 JA		15 JAN 2024	
Sr. No.			Specifications	R		Results	
10	Residual solvents by GC-HS Ethyl acetate		Not more than 5000 ppm	^	288 p	mao	
	Toluene		Not more than 890 ppm		32 ppm		
					Not Detected.		
	n-Butyl acetate		Not more than 5000 ppm				
11	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 ii)Total combined yeasts and molds count			ARMA.				
		microbial	Not more than 10 ³ cfu/g		Less	than 10 cfu/g	
		•	Not more than 10 ² cfu/g		Less than 10 cfu/g		
	b) Test for specified microorganisms :						
Escherichia Coli		Coli	Should be absent per g		Absent		
13	Particle size b	y Malvern	d(0.9): Not more than 70 μr	n	61 µn	n	

Checked by: : 07810K3010 Date Date Date : 07 Marzo (9 Head QC (Designee) Head QA / Designee **Operating Personnel QC**

Approved by:

Emcure Pharmaceuticals Limited

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

Corporate Identity Number (CIN): U24231PN1981PLC024251

Emoure



Page No.: 4 of 4

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		

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

Compiled by :

Date

: 01evor 3010

Checked by : €

Date

:67 Manzola

Operating Personnel QC

Head QC / Designee

Approved by:

Date

Head QA / Designee

Emcure Pharmaceuticals Limited

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