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CERTIFICATE OF ANALYSIS

QUALITY ASSURANCE

Product Name: MYCOPHENOLATE MOFETIL Ph.Eur.	Page No. : 1 of 2
Batch No./Disp.Ref.No. : BS17001227/BF17002103	Manufacturing date : May 2017
Quantity : 0.500 kg	Retest date : April 2021
A.R. No. : 40000145702	Batch release date : 09/06/2017

Ph. Eur. & In-house Specification:

TESTS	OBSERVATIONS	LIMITS
Appearance	Almost white crystalline powder	A white or almost white, crystalline powder.
Solubility	Complies	Practically insoluble in Water, freely soluble in acetone, sparingly soluble in anhydrous ethanol.
Identification a. By IR b. By HPLC	 Complies Complies	 a. IR spectrum of sample should be concordant with that of Laboratory standard. b. The retention time of Mycophenolate mofetil peak in the related substances chromatogram of sample should match with that of peak identification chemical reference substances of Mycophenolate mofetil.
Appearance of solution	Complies	The solution is clear and colorless.
[1]Melting point	96.7°C	Between 95.0°C and 97.5°C
Loss on drying	0.15%	Not more than 0.50% w/w
Sulphated ash	0.04%	Not more than 0.10% w/w
Heavy metals	Less than 20 ppm	Not more than 0.002% (20 ppm)
[1]Related substances (by HPLC)	Below disregard limit Below disregard limit Below detection level Not detected Below detection level Below detection level Below detection level Below detection level Below disregard limit Below disregard limit	Mycophenolic Acid (Impurity F) - NMT 0.20% Impurity A - NMT 0.10% Impurity B - NMT 0.10% Impurity C - NMT 0.10% Impurity D - NMT 0.10% Impurity E - NMT 0.10% Impurity G - NMT 0.10% Impurity H - NMT 0.10% Any individual unknown impurity - NMT 0.050% Total impurities - NMT 0.50%

Prepared by : **Checked by :** **Approved by :**
Date : 17/07/2017 **Date:** 17/07/2017 **Date :** 17/07/2017
(Quality Assurance)

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Ph. Eur. ,In-house & Customer specification

TESTS	OBSERVATIONS	LIMITS
[2]Assay (by Potentiometry) : Content of Mycophenolate Mofetil	100.1%	Between 98.0% w/w and 102.0% w/w
[1,2]Assay (by HPLC): Content of Mycophenolate Mofetil	100.5%	Between 98.0% w/w and 102.0% w/w
[1]Residual solvents (by GC)	126 ppm Below detection level Below quantitation level	Ethyl acetate - NMT 1500 ppm Toluene - NMT 200 ppm Xylene - NMT 200 ppm
Particle size distribution	d(0.1) : 3.7 micron d(0.5) : 8.7 micron d(0.9) : 18.0 micron	For information
[3]Bacterial endotoxins	Less than 0.1 EU/mg	Not more than 0.2 EU/mg
[3]Microbial Examination: i) Total viable aerobic microbial count ii) Fungi iii) E. coli	 Less than 100 cfu/g Less than 10 cfu/g Absent	 NMT 100 cfu/g NMT 10 cfu/g Should be Absent in 1g
REMARKS: The sample complies with the above tests as per Ph. Eur., In-house & Customer specification. '1'- In-house specification. '2'- On dried basis. '3' Customer specification.		
Storage : Preserve in an airtight container, protected from light. Store at a temperature up to 25°C.		

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