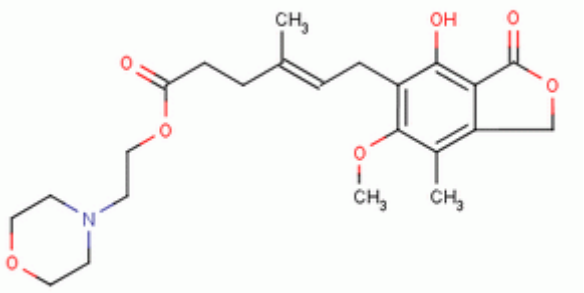
HANGZHOU DINGYAN CHEM CO.,LTD
TEL: 86-571-87157530,86465881,88025800, FAX:86-571-87156470
E-Mail:sales@dingyanchem.com,Web: www.dingyanchem.com

CERTIFICATE OF ANALYSIS

NO: DYC041708093

Product name	Mycophenolate mofetil,USP39
CAS Number	128794-94-5
Molecule Structure	
Molecule Formula	$C_{23}H_{31}NO_7$
Batch number	20170316
Manuf&Exp. Date	2017-03-16, 2019-03-15
Testing date	2017-03-17

Items	Standard	Result
Appearance	White or almost white crystalline powder.	White crystalline powder
Identification	1. Infrared Absorption 2. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Conform
Loss on drying	0.5 % max	0.04 %
Heavy metals	20 ppm max	Conform
Residue on ignition	0.1 % max	0.01 %
Assay(on the dried basis)	98.0 % to 102.0 %	99.7 %
Organic Impurities	Mycophenolic acid: 0.50 % max Mycophenolate Mofetil related compound A: 0.10% max Mycophenolate Mofetil related compound B: 0.10% max N-Oxide analog: 0.10% max 1-Morpholinoethoxy analog: 0.10% max Z- Mycophenolate mofetil 0.10% max	0.04% ND ND ND ND ND

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	O-Methyl analog: 0.10% max Methyl mycophenolate: 0.10% max Any single unspecified impurity: 0.10% max Total impurities: 0.70% max	ND ND ND 0.04%
Residual Solvent	Xylene: 2170ppm max Ethyl acetate: 5000ppm max Benzene: 2ppm max Chlorohydrin: 50ppm max 2-Morpholinoethanol: 1000ppm max	2170ppm max 5000ppm max 2ppm max 50ppm max 1000ppm max
Conclusion: Conform to the standard of USP39.		

Hangzhou Dingyan Chem Co.,Ltd.
Quality Control
Signature(s)

QUALITY CONTROL: Cristina CHECK:姚仙娟 INSPECTOR: 刘清风