

CERTIFICATE OF ANALYSIS

(Certificate No. KMM002025-01)

Release Date: 17/07/2024

Re-test Date: 16/07/2027

Mycophenolate Mofetil EP Impurity G

Identification

Chemical Name :

2-(Morpholin-4-yl)ethyl (4E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoate N-oxide (as per EP) 2-Morpholinoethyl (E)-6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate N-oxide (as per USP)

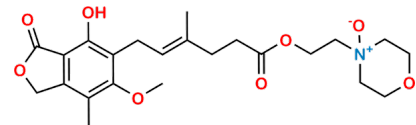
Alt. Name : Mycophenolate Mofetil N-Oxide (USP)

CAT No. : KMM002025

CAS No. : 224052-51-1

Molecular Formula : C23H31NO8

Molecular Weight : 449.5



Analytical Information

Batch No. : MYC-N-OXIDE-019-200

Solubility : Methanol

Description : Off White Solid

Mass : Confirm

HPLC Purity : 93.62 %

IR : Confirm

Weight Loss By TGA : 0.99 %

¹H NMR : Confirm

% Potency : 92.69 %

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.99(Weight Loss By TGA)] x [93.62(HPLC Purity)]/100 = 92.69 %

-Re-tested on 17.07.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		09/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		09/09/2024

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA