

CERTIFICATE OF ANALYSIS

(Certificate No. KMM002002-01)

Release Date: 17/05/2025

Re-test Date: 16/05/2028

Mycophenolate Mofetil EP Impurity C

Identification

Chemical Name :

(Z)-2-morpholinoethyl 6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoate

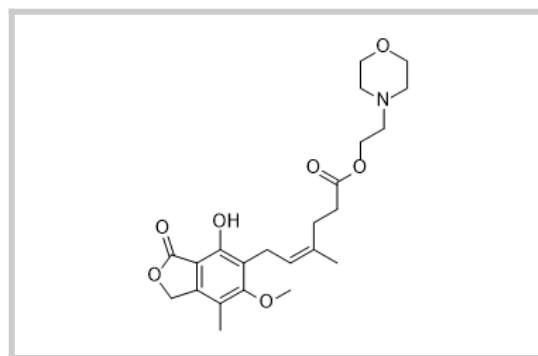
Alt. Name : Z-Mycophenolate mofetil (USP) ; cis Mycophenolate Mofetil

CAT No. : KMM002002

CAS No. : 2286278-51-9

Molecular Formula : C23H31NO7

Molecular Weight : 433.49



Analytical Information

Batch No. : M002002-073-419

Solubility : Acetonitrile

Description : Light Brown Thick Syrup

Mass : Confirm

HPLC Purity : 95.69 %

IR : Confirm

Weight Loss By TGA : 3.34 %

¹H NMR : Confirm

% Potency : 92.49 %

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 - 3.34(Weight Loss By TGA)] x [95.69(HPLC Purity)]/100 = 92.49 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/05/2025
Reviewed & Approved By	Quality Control	Ravi Patel		19/05/2025

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