

# CERTIFICATE OF ANALYSIS

(Certificate No. KMM002002-01)

Release Date: 19/10/2024

Re-test Date: 18/10/2027

## 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

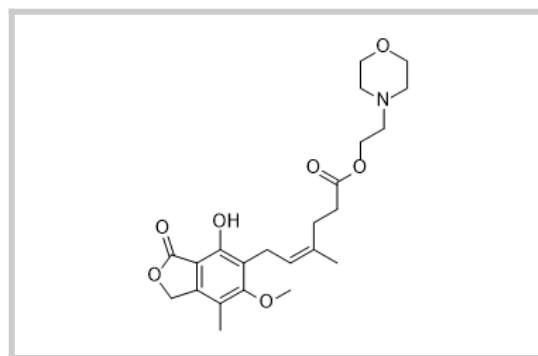
**Alt. Name** : Z-Mycophenolate mofetil (USP) ; cis Mycophenolate Mofetil

**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** : 93.48 %

**IR** : Confirm

**Weight Loss By TGA** : 0.47 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 93.04 %

### 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 - 0.47(Weight Loss By TGA)] x [93.48(HPLC Purity)]/100 = 93.04 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		19/03/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA