

CERTIFICATE OF ANALYSIS

(Certificate No. KMM002005-01)

Release Date: 17/07/2024

Re-test Date: 16/07/2027

Mycophenolate Mofetil EP Impurity E

Identification

Chemical Name :

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

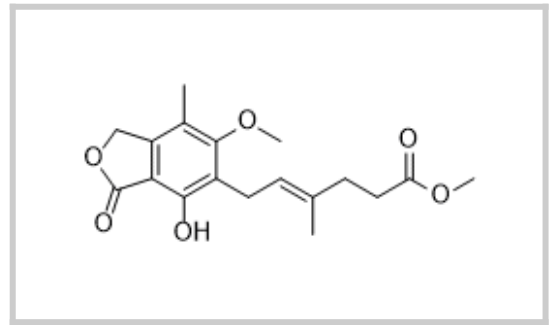
Alt. Name : Methyl mycophenolate (USP) ;
Mycophenolic acid methyl ester

CAT No. : KMM002005

CAS No. : 31858-66-9

Molecular Formula : C₁₈H₂₂O₆

Molecular Weight : 334.36



Analytical Information

Batch No. : MYC-METHYL-019-202

Solubility : ACN

Description : Off White Solid

Mass : Confirm

HPLC Purity : 98.29 %

IR : Confirm

Weight Loss By TGA : 0.34 %

¹H NMR : Confirm

% Potency : 97.96 %

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 = $[100 - 0.34(\text{Weight Loss By TGA})] \times [98.29(\text{HPLC Purity})]/100 = 97.96 \%$
-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, ¹H NMR, IR and TGA