

CERTIFICATE OF ANALYSIS

(Certificate No. KMM002022-02)

Release Date: 16/09/2024

Re-test Date: 15/09/2027

Mycophenolate Mofetil EP Impurity D

Identification

Chemical Name :

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

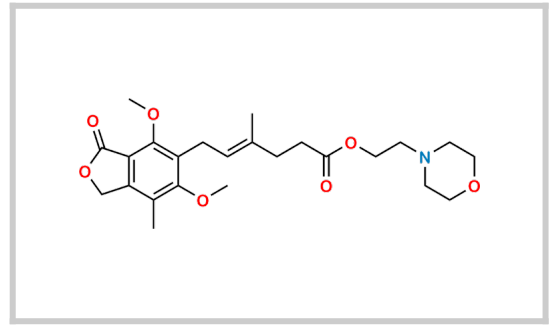
Alt. Name : O-Methyl Mycophenolate Mofetil (USP)

CAT No. : KMM002022

CAS No. : 1322681-37-7

Molecular Formula : C₂₄H₃₃N₁O₇

Molecular Weight : 447.5



Analytical Information

Batch No. : M002022-073-370

Description : Yellow Thick Syrup

HPLC Purity : 96.95 %

Weight Loss By TGA : 1.77 %

% Potency : 95.23 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

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 - 1.77(Weight Loss By TGA)] x [96.95(HPLC Purity)]/100 = 95.23 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		13/11/2024
Reviewed & Approved By	Quality Control	Jatin Patel		13/11/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA