

# 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)

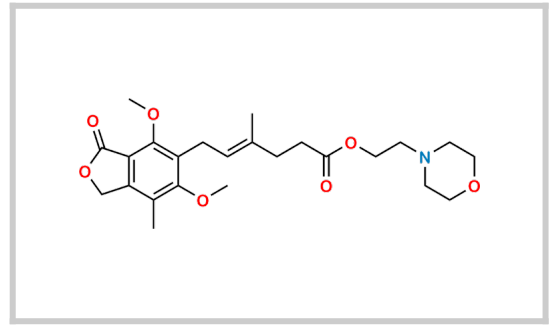
**Alt. Name** : O-Methyl Mycophenolate Mofetil (USP)

**CAT No.** : KMM002022

**CAS No.** : 1322681-37-7

**Molecular Formula** : C<sub>24</sub>H<sub>33</sub>N<sub>1</sub>O<sub>7</sub>

**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

**<sup>1</sup>H 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
<b>Prepared By</b>	Analytical	Jignesh Patel		13/11/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		13/11/2024

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