

# 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

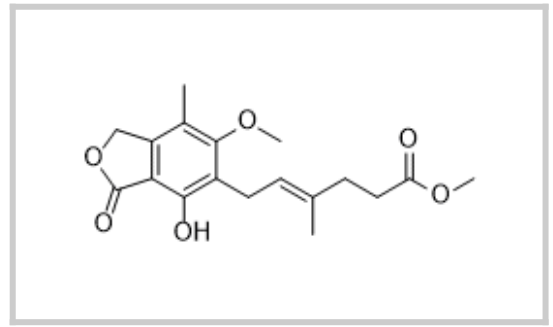
**Alt. Name** : Methyl mycophenolate (USP) ;  
Mycophenolic acid methyl ester

**CAT No.** : KMM002005

**CAS No.** : 31858-66-9

**Molecular Formula** : C<sub>18</sub>H<sub>22</sub>O<sub>6</sub>

**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 %

**<sup>1</sup>H 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

-Re-tested on 17.07.2024

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Parag Patel		09/09/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		09/09/2024

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