

# CERTIFICATE OF ANALYSIS

(Certificate No. KMM002025-01)

Release Date: 17/07/2024

Re-test Date: 16/07/2027

## Mycophenolate Mofetil EP Impurity G

### Identification

**Chemical Name :**

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

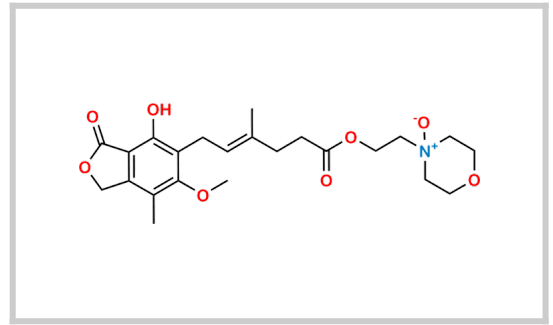
**Alt. Name** : Mycophenolate Mofetil N-Oxide (USP)

**CAT No.** : KMM002025

**CAS No.** : 224052-51-1

**Molecular Formula** : C<sub>23</sub>H<sub>31</sub>N<sub>0</sub>O<sub>8</sub>

**Molecular Weight** : 449.5



### Analytical Information

**Batch No.** : MYC-N-OXIDE-019-200

**Description** : Off White Solid

**HPLC Purity** : 93.62 %

**Weight Loss By TGA** : 0.99 %

**% Potency** : 92.69 %

**Solubility** : Methanol

**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

-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