

# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMM002004-02)

**Release Date:** 01/05/2025

**Re-test Date:** 30/04/2028

## **Mycophenolate Mofetil Impurity H**

### **Identification**

**Chemical Name :**

7-hydroxy-5-methoxy-4-methyl-6-(2-(2-methyl-5-oxotetrahydrofuran-2-yl)ethyl)isobenzofuran-1(3H)-one

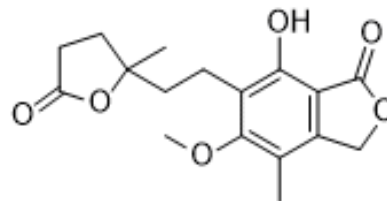
**Alt. Name** : Mycophenolate Mofetil USP Related Compound B ; Mycophenolic Lactone

**CAT No.** : KMM002004

**CAS No.** : 26675-76-3

**Molecular Formula** : C<sub>17</sub>H<sub>20</sub>O<sub>6</sub>

**Molecular Weight** : 320.34



### **Analytical Information**

**Batch No.** : M002026-091-363

**Description** : Off white solid

**HPLC Purity** : 99.90 %

**Weight Loss By TGA** : 0.32 %

**% Potency** : 99.58 %

**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 - 0.32(Weight Loss By TGA)] x [99.90(HPLC Purity)]/100 = 99.58 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		22/07/2025

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