

CERTIFICATE OF ANALYSIS

(Certificate No. KMM002004-01)

Release Date: 03/05/2024

Re-test Date: 02/05/2027

Mycophenolate Mofetil EP Impurity H

Identification

Chemical Name :

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

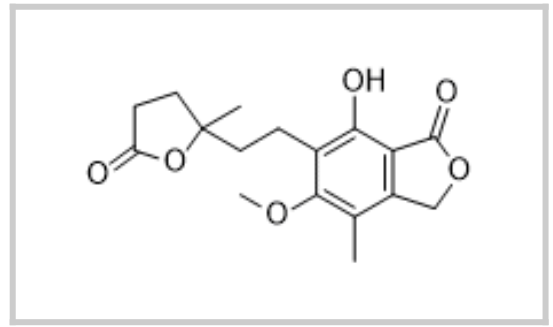
Alt. Name : Mycophenolate Mofetil USP Related Compound B ; Mycophenolic Lactone

CAT No. : KMM002004

CAS No. : 26675-76-3

Molecular Formula : C₁₇H₂₀O₆

Molecular Weight : 320.34



Analytical Information

Batch No. : KMPS/04/161

Description : Off White Solid

HPLC Purity : 98.34 %

Weight Loss By TGA : 1.18 %

% Potency : 97.18 %

Solubility : ACN

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 - 1.18(Weight Loss By TGA)] x [98.34(HPLC Purity)]/100 = 97.18 %

Remarks : COA Re-generated on 11.05.2024

-Re-tested on 03.05.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		09/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		09/09/2024

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