CERTIFICATE OF ANALYSIS

(Certificate No. KMM002022-02)

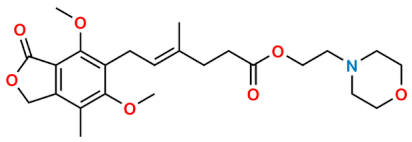
Release Date: 16/09/2024 **Re-test Date:** 15/09/2027

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	: C24H33NO7
Molecular Weight	: 447.5



Analytical Information

Batch No.	: M002022-073-370	**Solubility**	: Acetonitrile
Description	: Yellow Thick Syrup	**Mass**	: Confirm
HPLC Purity	: 96.95 %	**IR**	: Confirm
Weight Loss By TGA	: 1.77 %	**1H NMR**	: Confirm
% Potency	: 95.23 %		

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
Prepared By	Analytical	Jignesh Patel		13/11/2024
Reviewed & Approved By	Quality Control	Jatin Patel		13/11/2024

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA