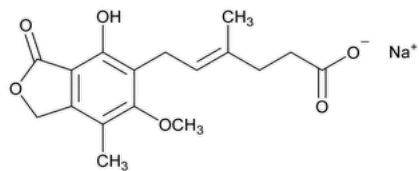


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Mycophenolate Sodium



$C_{17}H_{19}NaO_6$ 342.32
4-Hexenoic acid, 6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-, monosodium salt, (E)-;
Sodium (E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoate CAS RN[®]: 37415-62-6.

DEFINITION
Mycophenolate Sodium contains NLT 98.0% and NMT 102.0% of mycophenolate sodium ($C_{17}H_{19}NaO_6$), calculated on the anhydrous basis.

- IDENTIFICATION**
- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A, 197K, or 197M
 - **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Protect solutions from light.

Solution A: Acetonitrile, phosphoric acid, and water (100:0.2:900)

Solution B: Acetonitrile, phosphoric acid, and water (800:0.2:200)

Mobile phase: See [Table 1](#). Return to original conditions, and re-equilibrate the system.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
35	10	90
40	10	90

Diluent: Methanol and water (1:9)

Standard solution: 0.08 mg/mL of [USP Mycophenolate Sodium RS](#) in *Diluent*. Protect from light.

Sample solution: 0.08 mg/mL of Mycophenolate Sodium in *Diluent*. Protect from light.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 216 nm

Column: 3-mm × 25-cm; 5-μm packing L1

Column temperature: 50°

Flow rate: 0.8 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.73%

Tailing factor: 0.7–1.5

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mycophenolate sodium ($C_{17}H_{19}NaO_6$) in the portion of Mycophenolate Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Mycophenolate Sodium RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Mycophenolate Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• ORGANIC IMPURITIES

Protect solutions from light.

Mobile phase, Diluent, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

System suitability stock solution 1: 0.02 mg/mL of [USP Mycophenolate Mofetil Related Compound B RS](#) prepared as follows. Transfer [USP Mycophenolate Mofetil Related Compound B RS](#) to a suitable volumetric flask and dilute in methanol equivalent to 10% of the final volume, and then dilute with water to volume.

System suitability stock solution 2: Transfer 4.0 mL of *System suitability stock solution 1* to a 100-mL volumetric flask and dilute with *Diluent* to volume.

System suitability solution: 0.8 µg/mL of [USP Mycophenolate Mofetil Related Compound B RS](#) and 0.08 mg/mL of [USP Mycophenolate Sodium RS](#) prepared by dissolving a suitable amount of [USP Mycophenolate Sodium RS](#) in *System suitability stock solution 2*

Sensitivity solution: 0.024 µg/mL of [USP Mycophenolate Sodium RS](#) in *Diluent* from *Standard solution*

System suitability

Samples: *Standard solution*, *System suitability solution*, and *Sensitivity solution*

Suitability requirements

Resolution: NLT 1.5 between the mycophenolate mofetil related compound B and mycophenolate peaks, *System suitability solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Mycophenolate Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of mycophenolate from the *Standard solution*

C_S = concentration of [USP Mycophenolate Sodium RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Mycophenolate Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: See [Table 2](#). Disregard any impurity peak less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Mycophenolate mofetil related compound B ^a	0.9	0.1
Mycophenolate	1.0	—
Any individual unspecified impurity	—	0.07
Total impurities	—	0.4

^a (RS)-7-Hydroxy-5-methoxy-4-methyl-6-[2-(5-methyl-2-oxo-tetrahydrofuran-5-yl)ethyl]-3H-isobenzofuran-1-one.