

Mycophenolic Acid Delayed-Release Tablets

DEFINITION
Mycophenolic Acid Delayed-Release Tablets contain an amount of mycophenolate sodium equivalent to NLT 95.0% and NMT 105.0% of the labeled amount of mycophenolic acid ($C_{17}H_{20}O_6$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum 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: Dissolve 21 g of [citric acid](#) in a suitable volume of water, add 200 mL of 1 M [sodium hydroxide](#) solution, and dilute with [water](#) to 1 L.

Buffer: *Solution A* and 0.1 M [hydrochloric acid](#) (399:601)

Solution B: Acetonitrile, *Buffer*, and [water](#) (40:15:45)

Solution C: Acetonitrile and *Buffer* (85:15)

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

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	100	0
9	100	0
18	0	100
22	0	100

Diluent: *Solution B*

Standard solution: 0.385 mg/mL of [USP Mycophenolate Sodium RS](#) in *Diluent*. Stir magnetically for at least 60 min to aid dissolution.

Sample stock solution: Nominally equivalent to 9 mg/mL of mycophenolic acid in *Diluent* prepared as follows. Transfer NLT 25 Tablets to a volumetric flask and add *Diluent* to volume. Add a stirring bar and stir vigorously for at least 60 min. Centrifuge a portion of the suspension and use the clear supernatant.

Sample solution: Nominally equivalent to 0.36 mg/mL of mycophenolic acid in *Diluent* from *Sample stock solution*

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

Mode: LC

Detector: UV 251 nm or diode array. [NOTE—Use a diode array detector to perform *Identification B*.]

Column: 4.6-mm × 25-cm; 5-μm packing [L7](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of mycophenolic acid ($C_{17}H_{20}O_6$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of mycophenolate 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 = nominal concentration of mycophenolic acid in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of mycophenolic acid, 320.34

M_{r2} = molecular weight of mycophenolate sodium, 342.32

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Protect solutions from light.

Acid stage

Acid stage medium: 0.1 N [hydrochloric acid](#); 750 mL

Apparatus 2: 50 rpm

Time: 2 h

Determine the percentage of the labeled amount of mycophenolic acid ($C_{17}H_{20}O_6$) dissolved by using one of the following procedures.

Spectrophotometric procedure

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Standard solution: Transfer [USP Mycophenolate Sodium RS](#) to a suitable volumetric flask, dissolve in [methanol](#) equivalent to 5% of the final volume, and dilute with *Acid stage medium* to volume to obtain the solution having the following concentrations:

For Tablets labeled to contain 180 mg of mycophenolic acid: 0.0128 mg/mL of [USP Mycophenolate Sodium RS](#)

For Tablets labeled to contain 360 mg of mycophenolic acid: 0.0256 mg/mL of [USP Mycophenolate Sodium RS](#)

Sample solution: Centrifuge portions of the solution under test or pass through a suitable glass fiber filter of 1- μ m pore size.

Instrumental conditions

Mode: UV

Analytical wavelength: 250 nm

Cell path length

For Tablets containing 180 mg of mycophenolic acid per Tablet: 0.2 cm

For Tablets containing 360 mg of mycophenolic acid per Tablet: 0.1 cm

Blank: *Acid stage medium*

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of mycophenolic acid ($C_{17}H_{20}O_6$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

L = label claim (mg/Tablet)

