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Mycophenolate Mofetil Tablets

DEFINITION

Mycophenolate Mofetil Tablets contain NLT 94.0% and NMT 105.0% of the labeled amount of mycophenolate mofetil ($C_{23}H_{31}NO_7$).

IDENTIFICATION

Change to read:

- **A.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2023)
- **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

Change to read:

• PROCEDURE

Phosphoric acid solution: [Phosphoric acid](#) and [water](#) (3:50)

Triethylamine solution: Transfer 3 mL of [triethylamine](#) to 1000 mL of [water](#). Adjust with *Phosphoric acid solution* to a pH of 5.3.

Mobile phase: [Acetonitrile](#) and *Triethylamine solution* (55:45)

Standard solution: 0.125 mg/mL of [USP Mycophenolate Mofetil RS](#) in [acetonitrile](#)

▲**Sample stock solution:** Nominally 2.5 mg/mL of mycophenolate mofetil prepared as follows. Transfer Tablets, equivalent to 2.5 g of mycophenolate mofetil, to a 1000-mL volumetric flask. Add 100 mL of [water](#) and shake mechanically for a minimum of 15 min. Add 700 mL of [acetonitrile](#), sonicate for 15 min, and shake mechanically for 20 min. Dilute with [acetonitrile](#) to volume.▲ (USP 1-Aug-2023)

Sample solution: ▲Nominally 0.125 mg/mL of mycophenolate mofetil in [acetonitrile](#) from *Sample stock solution*. Pass through a nylon filter of 0.45-μm pore size and discard the first 5 mL of the filtrate.▲ (USP 1-Aug-2023)

Chromatographic system

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

Mode: LC

Detector: UV 250 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Aug-2023)

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

Temperatures

Column: 45°

Autosampler: 10 ± 5°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

▲**Run time:** NLT 3 times the retention time of mycophenolate mofetil peak▲ (USP 1-Aug-2023)

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mycophenolate mofetil ($C_{23}H_{31}NO_7$) in the portion of Tablets taken:

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

r_U = peak response of mycophenolate mofetil from the *Sample solution*

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

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

C_U = nominal concentration of mycophenolate mofetil in the *Sample solution* (mg/mL)

Acceptance criteria: 94.0%–105.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Times: 5 and 15 min

Standard solution: 0.55 mg/mL of [USP Mycophenolate Mofetil RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Instrumental conditions

▲(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)▲ (USP 1-Aug-2023)

Mode: UV

Analytical wavelength: 304 nm

Path length: 0.1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of mycophenolate mofetil ($C_{23}H_{31}NO_7$) dissolved at each time point (i):

$$\text{Result} = (A_U/A_S) \times C_S$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

Calculate the percentage of the labeled amount of mycophenolate mofetil ($C_{23}H_{31}NO_7$) dissolved at each time point (i):

$$\text{Result}_1 = C_i \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$

C_i = concentration of mycophenolate mofetil in the portion of sample withdrawn at the specified time (mg/mL)

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

V_S = volume of the *Sample solution* withdrawn at each time point (mL)

Tolerances: See [Table 1](#).

Table 1

Time Point (i)	Time (min)	Tolerances (Q)
1	5	NLT 75%
2	15	NLT 85%

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#); 900 mL, deaerated

Apparatus 2: 50 rpm

Times: 5 and 15 min

Diluted phosphoric acid: Transfer 5 mL of [phosphoric acid](#) to a 25-mL volumetric flask. Dilute with [water](#) to volume.

Buffer: 3.0 mL/L of [triethylamine](#) in [water](#). Adjust with *Diluted phosphoric acid* to a pH of 5.3.

Mobile phase: [Acetonitrile](#) and *Buffer* (45:55)

Diluent: [Acetonitrile](#) and *Buffer* (20:80)

Standard stock solution: 0.56 mg/mL of [USP Mycophenolate Mofetil RS](#) in *Medium*