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Mycophenolate Mofetil for Injection

DEFINITION

Mycophenolate Mofetil for Injection contains an amount of Mycophenolate Mofetil Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of mycophenolate mofetil ($C_{23}H_{31}NO_7$).

IDENTIFICATION

Change to read:

• **▲A.▲** (USP 1-MAY-2019) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲• **B.** 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-May-2019)

ASSAY

Change to read:

• PROCEDURE

Protect solutions from light.

Buffer 1: Transfer 10 mL of [triethylamine](#) to a 1000-mL volumetric flask containing about 950 mL of [water](#) and mix. Adjust with [phosphoric acid](#) to a pH of 7.2, and dilute with [water](#) to volume.

Buffer 2: Transfer 10 mL of [triethylamine](#) to a 1000-mL volumetric flask containing about 950 mL of [water](#) and mix. Adjust with [phosphoric acid](#) to a pH of 3.0, and dilute with [water](#) to volume.

Solution A: *Buffer 1* and [water](#) (4:9)

Diluent: [Acetonitrile](#), *Buffer 2*, and [water](#) (7:4:9)

Mobile phase: [Acetonitrile](#) and *Solution A* (3:7)

Standard stock solution: 1.0 mg/mL of [USP Mycophenolate Mofetil RS](#) in *Diluent* prepared as follows. Transfer a known quantity of [USP Mycophenolate Mofetil RS](#) to a suitable volumetric flask, add [acetonitrile](#) equivalent to about 10% of the final volume, sonicate for about 5 min or until the solid dissolves, and dilute with *Diluent* to volume.

Standard solution: 0.4 mg/mL of [USP Mycophenolate Mofetil RS](#) in *Diluent* from *Standard stock solution*

Sample stock solution: Nominally equivalent to 10 mg/mL of mycophenolate mofetil prepared as follows. Constitute each of the containers of Mycophenolate Mofetil for Injection with 14 mL of 5% dextrose injection. Quantitatively transfer the contents of all vials, the combined contents of which are equivalent to about 2 g of mycophenolate mofetil, to a 200-mL volumetric flask, and dilute with [water](#) to volume.

Sample solution: Nominally equivalent to 0.4 mg/mL of mycophenolate mofetil in *Diluent* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 249 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2019)

Column: 4.6-mm × 25-cm; 5-μm packing [L11](#)

Temperatures

Autosampler: 5°

Column: 45°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

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 Mycophenolate Mofetil for Injection 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 Mofetil RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Protect solutions from light.

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

System suitability solution: 0.01 mg/mL of [USP Mycophenolate Mofetil Related Compound A RS](#) and 0.01 mg/mL of [USP Mycophenolate Mofetil Related Compound B RS](#) in *Diluent*

Sensitivity solution: 0.2 µg/mL in *Diluent* from the *Standard solution*

System suitability

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

[NOTE—The relative retention times for mycophenolate mofetil related compound A and mycophenolate mofetil related compound B are 0.40 and 0.46, respectively, measured with respect to mycophenolate mofetil.]

Suitability requirements

Resolution: NLT 2.0 between mycophenolate mofetil related compound A and mycophenolate mofetil related compound B, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—The run time for the *Sample solution* is NLT 1.5 times the retention time of the mycophenolate mofetil peak.]

Calculate the percentage of each impurity in the portion of Mycophenolate Mofetil for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each individual impurity 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)

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#). ▲The reporting threshold is 0.05%.▲ (USP 1-May-2019)

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Mycophenolic acid ^a	0.12	1.4	1.1
Mycophenolate mofetil	1.00	—	



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