

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2021
 Document Type: USP Monographs
 DocId: GUID-9ACFADE9-4B1F-4E6C-9E4C-5F892C5742EE_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M17665_03_01
 DOI Ref: c2457

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Cilostazol Tablets

DEFINITION

Cilostazol Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of cilostazol ($C_{20}H_{27}N_5O_2$).

IDENTIFICATION

Delete the following:

▲ • **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197S

Standard solution: 100 mg/mL of [USP Cilostazol RS](#) in chloroform

Sample solution: Transfer the equivalent of 100 mg of cilostazol from finely powdered Tablets into a glass container. Add 1 mL of chloroform, shake for 1 min, and pass through a suitable filter of 0.5-μm or finer pore size. ▲ (USP 1-May-2021)

Add the following:

▲ • **A.** The UV spectrum of the major peak for cilostazol of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-May-2021)

• **B.** The retention time of the major peak for cilostazol of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

▲ **Mobile phase:** [Acetonitrile](#), [methanol](#), and [water](#) (35:15:50)

Standard solution: 0.1 mg/mL of [USP Cilostazol RS](#) in *Mobile phase* prepared as follows. Transfer a quantity of [USP Cilostazol RS](#) to a suitable volumetric flask. Add *Mobile phase* to 80% of the total volume and sonicate for at least 15 min. Dilute with *Mobile phase* to volume, and mix well.

Sample stock solution: Transfer 10 Tablets to a 500-mL volumetric flask. Add *Mobile phase* to 80% of the total volume and shake mechanically for 30 min. Sonicate for at least 5 min. Dilute with *Mobile phase* to volume, and mix well.

Sample solution: Nominally 0.1 mg/mL of cilostazol in *Mobile phase* from the *Sample stock solution*. Pass through a suitable nylon filter of 0.45-μm pore size. Discard the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 25 μL

Run time: NLT 2 times the retention time of the cilostazol peak

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 cilostazol ($C_{20}H_{27}N_5O_2$) in the portion of Tablets taken:

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



r_U = peak response of cilostazol from the *Sample solution*

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

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

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

▲ (USP 1-May-2021)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

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

Test 1

Medium: 0.30% [sodium lauryl sulfate](#) in [water](#); 900 mL

Apparatus 2: 75 rpm

Time: 60 min

▲ **Standard stock solution:** 0.28 mg/mL of [USP Cilostazol RS](#) in [methanol](#) ▲ (USP 1-May-2021)

Standard solution: ▲ 5.6 µg/mL of [USP Cilostazol RS](#) in *Medium* from the *Standard stock solution* ▲ (USP 1-May-2021)

Sample solution: ▲ Nominally 5.6 µg/mL of cilostazol in *Medium* prepared as follows. Pass NLT 20 mL of the solution under test through a suitable filter of 0.45-µm pore size, discarding the first 10 mL. Dilute with *Medium*. ▲ (USP 1-May-2021)

Instrumental conditions

Mode: UV

Analytical wavelength: 257 nm

Cell: 1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲ the labeled amount of ▲ (USP 1-May-2021) cilostazol $(C_{20}H_{27}N_5O_2)$ ▲ (USP 1-May-2021) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

▲ D = dilution factor for the *Sample solution* ▲ (USP 1-May-2021)

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of cilostazol $(C_{20}H_{27}N_5O_2)$ ▲ (USP 1-May-2021) is dissolved.

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

Medium: 0.3% [sodium lauryl sulfate](#) in [water](#); 900 mL, deaerated

Apparatus 2: 75 rpm

Time: 30 min

▲ **Standard stock solution:** 1.1 mg/mL of [USP Cilostazol RS](#) in [methanol](#) ▲ (USP 1-May-2021)

Standard solution: ▲ $(L/900)$ mg/mL of [USP Cilostazol RS](#) in 0.5% [sodium lauryl sulfate](#) in [water](#) from the *Standard stock solution*, where L is the label claim in mg/Tablet ▲ (USP 1-May-2021)

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

Mode: UV

Analytical wavelength: 258 nm