Add the following:

**Cilostazol Tablets**

Cilostazol Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of cilostazol (C₂₀H₂₇N₅O₂).

**Packaging and storage**—Preserve in tight and light-resistant containers. Store at controlled room temperature.

**USP Reference standards** (11)—USP Cilostazol RS.

**Identification**—

A: Infrared Absorption (197S)—

Standard solution—Prepare a solution of USP Cilostazol RS in chloroform having a known concentration of 100 mg per mL.

Test solution—Accurately transfer a quantity of finely powdered Tablets, equivalent to about 100 mg of cilostazol, into a glass container. Add 1 mL of chloroform, shake for 1 minute, and filter through a 0.5-µm or finer filter.

B: The retention time of the cilostazol peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.

**Add the following:**

**Dissolution (711)—**

**TEST 1**

Medium: 0.30% sodium lauryl sulfate in water; 900 mL.

Apparatus 2: 75 rpm.

Time: 60 minutes.

Determine the amount of C₂₀H₂₇N₅O₂ dissolved using the following method.

Standard solution—Transfer about 28 mg, accurately weighed, of USP Cilostazol RS to a 100-mL volumetric flask, dissolve in and dilute with methanol to volume, and mix well. Transfer 4.0 mL of this solution to a 200-mL volumetric flask, dilute with Medium to volume, and mix well.

Test solution—Pass not less than 20 mL of the solution under test through a suitable 0.45-µm filter, discarding the first 10 mL of filtrate. Dilute with Medium in such a way as to obtain a final theoretical concentration of about 5.6 µg of cilostazol per mL, considering complete dissolution of the label claim.

Procedure—Determine the amount of C₂₀H₂₇N₅O₂ dissolved by employing UV absorption at the wavelength of about 257 nm on the Test solution in comparison with the Standard solution, using a 1-cm cell and Medium as the blank. Calculate the amount of C₂₀H₂₇N₅O₂ dissolved, in percentage, by the formula:

\[ C_5 = \frac{A_U 	imes 900 	imes 100}{A_S 	imes L} \]

in which \( C_5 \) is the concentration, in mg per mL, of USP Cilostazol RS in the Standard solution; \( A_U \) and \( A_S \) are the absorbances obtained from the Test solution and the Standard solution, respectively; 900 is the volume, in mL, of Medium; 100 is the conversion factor to percentage; and \( L \) is the Tablet label claim, in mg.

**Tolerances**—Not less than 80% (Q) of the labeled amount of C₂₀H₂₇N₅O₂ is dissolved in 60 minutes.

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

Medium, Apparatus 2, Standard solution, Test solution, and Procedure—Proceed as directed for Test 1.

Time: 30 minutes.

Tolerances—Not less than 75% (Q) of the labeled amount of C₂₀H₂₇N₅O₂ is dissolved in 30 minutes.● RB 1-Mar-2009

**Uniformity of dosage units (905):** meet the requirements.

**Assay**—

Mobile phase—Prepare a filtered and degassed mixture of water, acetonitrile, and methanol (10:7:3). Make adjustments if necessary (see System Suitability under Chromatography (621)).

Internal standard solution—Prepare a solution of benzophenone in methanol having a known concentration of 4 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Cilostazol RS and an appropriate amount of Internal standard solution and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 0.1 mg of USP Cilostazol RS and 0.04 mg of the internal standard per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of cilostazol, to a suitable volumetric flask and add an appropriate quantity of Internal standard solution. Dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 0.1 mg of USP Cilostazol RS and 0.04 mg of the internal standard per mL.

Assay—

Determine the amount of C₂₀H₂₇N₅O₂ dissolved, in percentage, by the formula:

\[ \frac{100(C_1 / C_U)(r_U / r_S)}{100} \]

in which \( C_1 \) is the concentration, in mg per mL, of USP Cilostazol RS in the Standard preparation; \( C_U \) is the concentration of cilostazol in the Assay preparation, based on the labeled quantity per Tablet and the extent of dilution; and \( r_U \) and \( r_S \) are the peak responses of cilostazol obtained from the Assay preparation and the Standard preparation, respectively.■1S (USP31)