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 ($C_{20}H_{27}N_5O_2$).

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 $C_{20}H_{27}N_5O_2$ 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 $C_{20}H_{27}N_5O_2$ 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 $C_{20}H_{27}N_5O_2$ dissolved, in percentage, by the formula:

$$C_S \times A_U \times 900 \times 100 / (A_S \times L)$$

in which C_S 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 $C_{20}H_{27}N_5O_2$ 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 $C_{20}H_{27}N_5O_2$ 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. Pass a portion of this solution through a membrane filter having a 0.5-µm or finer porosity, and use the filtrate.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 150-cm column that contains packing L1. The flow rate is about 1 mL per minute. The column temperature is maintained at ambient temperature. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the resolution, R, between the cilostazol and benzophenone peaks eluted in this order is not less than 9.0; and the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the percentage of the labeled amount of $C_{20}H_{27}N_5O_2$ in the portion of Tablets taken by the formula:

$$100(C_S / C_U)(r_U / r_S)$$

in which C_S 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*)