Time (minutes)	*Solution A* (%)	*Solution B* (%)	Elution
11.5–11.6	25→100	75→0	linear gradient
11.6–13	100	0	re-equilibration

Chromatograph the *System suitability preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.60 for lovastatin and 1.0 for simvastatin; and the resolution, *R,* between simvastatin and lovastatin is greater than 3. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 5 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 quantity, in mg, of $C_{25}H_{38}O_5$ in the portion of Simvastatin taken by the formula:

$$VC(r_U / r_S)$$

in which V is the volume, in mL, of the *Assay preparation; C* is the concentration, in mg per mL, of USP Simvastatin RS in the *Standard preparation;* and r_U and r_S are the responses of the simvastatin peak obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Simvastatin Tablets

» Simvastatin Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of simvastatin ($C_{25}H_{38}O_5$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Simvastatin RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Dissolution ⟨711⟩**—**

Medium: pH 7.0 buffer solution containing 0.5% sodium dodecyl sulfate in 0.01 M sodium phosphate prepared by dissolving 30 g of sodium dodecyl sulfate and 8.28 g of monobasic sodium phosphate in 6000 mL of water, and adjusting with 50% (w/v) sodium hydroxide solution to a pH of 7.0; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Prewashed manganese dioxide—Transfer 10 g of manganese dioxide to a suitable container, and treat as follows. Add 50 mL of *Dissolution Medium,* and shake vigorously for 5 minutes. Centrifuge, decant the supernatant layer, and discard. Repeat twice, first with *Dissolution Medium* and then with water. Dry the solid at 100° for 1 hour before use.

Test solution—Transfer a filtered portion of the solution under test to a centrifuge tube containing about 10 mg of *Prewashed manganese dioxide* per mL of transferred solution under test, and mix. Allow the mixture to stand for 30 minutes with occasional shaking, centrifuge, and use a portion of the clear supernatant as the *Test solution*.

Blank—Proceed as directed for *Test solution*, except to use the *Dissolution Medium*.

Procedure—Determine the amount of $C_{25}H_{38}O_5$ dissolved from the difference between the UV absorbances at the wavelengths of maximum and minimum absorbance at about 247 nm and 257 nm, respectively, on filtered portions of the *Test solution*, in comparison with a Standard solution having a known concentration of USP Simvastatin RS in the same *Medium* treated in the same way as the solution under test, each solution corrected for the *Blank*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{25}H_{38}O_5$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Diluting solution—Add 3.0 mL of glacial acetic acid to 900 mL of water. Adjust with 5 N sodium hydroxide to a pH of 4.0, and dilute with water to 1000 mL. To 200 mL of this solution, add 800 mL of acetonitrile, and mix.

Buffer solution—Dissolve 3.9 g of monobasic sodium phosphate in 900 mL of water. Adjust, if necessary, with either 50% sodium hydroxide or 85% phosphoric acid to a pH of 4.5, dilute with water to 1000 mL, and mix.

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and *Buffer solution* (65:35). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Simvastatin RS in *Diluting solution*, and dilute quantitatively, and stepwise if necessary, with *Diluting solution* to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer 10 Tablets to a 250-mL volumetric flask. Add a small volume of water (not more than 10 mL), and swirl to disintegrate the Tablets. Dilute with *Diluting solution* to volume, sonicate for 15 minutes, and cool to room temperature. If necessary, dilute with *Diluting solution* to volume. Centrifuge a portion of the mixture, and dilute a portion of the clear supernatant with *Diluting solution* to obtain a solution having a concentration of about 0.1 mg of simvastatin per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 238-nm detector and a 4.6-mm × 25-cm column containing packing L1 and maintained at a temperature of 45°. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the capacity factor, k', is not less than 3.0; the column efficiency is not less than 4500 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

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 of the major peaks. Calculate the quantity, in mg, of simvastatin ($C_{25}H_{38}O_5$) in each Tablet taken by the formula:

$$(L / D)C(r_U / r_S)$$

in which L is the labeled quantity, in mg, of simvastatin in each Tablet; D is the concentration, in mg per mL, of simvastatin in the *Assay preparation; C* is the concentration, in mg per mL, of USP Simvastatin RS in the *Standard preparation;* and r_U and r_S are the peak areas of simvastatin obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Sincalide for Injection

» Sincalide for Injection is a sterile, synthetically prepared C-terminal octapeptide of cholecystokinin and sodium chloride. It contains not less than 85.0 percent and not more than 125.0 percent of the labeled amount of sincalide ($C_{49}H_{62}N_{10}O_{16}S_3$).

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass.

Labeling—Label it to state that it is to be used within 24 hours after constitution.