Calculate the percentage of the labeled amount of sennosides in the *Sample* taken:

$$\text{Result} = (I_U/I_S) \times (C_S/C_U) \times 100$$

I_U = fluorescence value observed in the *Sample solution*
I_S = fluorescence value observed in the *Standard solution*
C_S = concentration of USP Sennosides RS in the *Standard solution*, corrected for loss on drying (mg/mL)
C_U = concentration of sennosides in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of sennosides

CONTAMINANTS

- **HEAVY METALS,** *Method II* ⟨**231**⟩**:** 60 µg/g

SPECIFIC TESTS

- **pH** ⟨**791**⟩**:** 6.3–7.3, in a 100-mg/mL solution
- **RESIDUE ON IGNITION** ⟨**281**⟩**:** 5.0%–8.0%, ignited at 800 ± 25°, the use of sulfuric acid being omitted
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample in a vacuum at 100° to constant weight: it loses NMT 5.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store protected from light and moisture, at controlled room temperature.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Sennosides RS

Sennosides Tablets

DEFINITION

Sennosides Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of Sennosides.

IDENTIFICATION

- **A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST**
  Solvent: Ethyl acetate, *n*-propyl alcohol, and water (1:1:1). Shake well, and discard the upper layer.
  Standard solution: 1 mg/mL of USP Sennosides RS in *Solvent*
  Sample solution: Shake a portion of finely powdered Tablets equivalent to 20 mg of sennosides with 20 mL of *Solvent*.
  Chromatographic system
  (See *Chromatography* ⟨621⟩*, Thin-Layer Chromatography*.)
  Adsorbent: 0.25-mm layer of chromatographic silica gel mixture
  Application volume: 20 µL
  Developing solvent system: Ethyl acetate, *n*-propyl alcohol, and water (4:4:3)
  Analysis: Proceed as directed in the chapter. Apply the solutions, as 1-cm streaks, on a line 2.5 cm from the bottom edge of a thin-layer chromatographic plate. Examine the plate under long-wavelength UV light. Expose the plate to ammonium hydroxide vapor until color develops (about 5 min). Cover the plate with a piece of glass, and heat at 120° for 5 min.
  Acceptance criteria: The two most prominent spots from the *Sample solution* correspond in color and mobility to those from the *Standard solution*.

ASSAY

- **PROCEDURE**
  Buffer: Dissolve 4.54 g of monobasic potassium phosphate in water to make 500 mL of solution. Dissolve 4.73 g of anhydrous dibasic sodium phosphate in water to make 500 mL of solution. Mix 38.9 mL of the monobasic potassium phosphate solution with 61.1 mL of the dibasic sodium phosphate solution. Adjust, if necessary, to a pH of 7.0 with the dibasic sodium phosphate solution.
  Borate solution: 37.9 g/L of sodium borate in water
  Sodium dithionite solution: 15 g/L of sodium dithionite in water
  Standard solution: 1 mg/mL of USP Sennosides RS in *Buffer*. Dissolve with the aid of an ultrasonic bath.
  Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 25 mg of sennosides, to a 25-mL volumetric flask. Add 20 mL of *Buffer*, and sonicate to dissolve. Add additional *Buffer* to volume. Centrifuge the resulting suspension for 15 min at 3500 rpm. Use the supernatant.
  Instrumental conditions
  (See *Spectophotometry and Light-Scattering* ⟨851⟩*, Fluorescence Spectrophotometry*.)
  Mode: Fluorescence
  Excitation wavelength: 392 nm
  Emission wavelength: 505 nm
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Pipet 1-mL portions of the *Standard solution* and the *Sample solution* into separate 100-mL volumetric flasks, and dilute with *Borate solution* to volume. Transfer 5.0-mL portions of each of the resulting solutions to separate low-actinic glass, 50-mL volumetric flasks, and add 15 mL of *Borate solution* and 15.0 mL of *Sodium dithionite solution*. Pass nitrogen through the solutions, seal the flasks with nitrogen-filled balloons, and heat in a water bath for 30 min. Cool the flasks for 15 min in a water bath thermostatically controlled at 20°. Dilute the solutions with *Borate solution* to volume. Determine without delay the fluorescence intensities of the resulting solutions, for which the time elapsed between the addition of *Sodium dithionite solution* and the measurement is the same.
  Calculate the percentage of the labeled amount of sennosides in the portion of Tablets taken:

$$\text{Result} = (I_U/I_S) \times (C_S/C_U) \times 100$$

I_U = fluorescence value observed in the *Sample solution*
I_S = fluorescence value observed in the *Standard solution*
C_S = concentration of USP Sennosides RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of sennosides in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

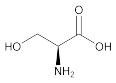
PERFORMANCE TESTS

- **DISSOLUTION** ⟨**711**⟩
  Medium: Water; 900 mL
  Apparatus 1: 100 rpm
  Time: 120 min
  Analysis: Determine the amount of sennosides dissolved, using the procedure set forth in the *Assay*, making any necessary volumetric adjustments.
  Tolerances: NLT 75% (*Q*) of the labeled amount of sennosides is dissolved.

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS
• **PACKAGING AND STORAGE:** Preserve in well-closed containers.
• **USP REFERENCE STANDARDS ⟨11⟩**
USP Sennosides RS

Serine



$C_3H_7NO_3$ 105.09
L-Serine [56-45-1].

DEFINITION
Serine contains NLT 98.5% and NMT 101.5% of L-serine ($C_3H_7NO_3$), calculated on the dried basis.

IDENTIFICATION
• **A. INFRARED ABSORPTION ⟨197K⟩**

ASSAY
• **PROCEDURE**
Sample: 100 mg of Serine
Blank: Mix 3 mL of formic acid and 50 mL of glacial acetic acid.
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.1 N perchloric acid VS
Endpoint detection: Potentiometric
Analysis: Dissolve the *Sample* in 3 mL of formic acid and 50 mL of glacial acetic acid. Titrate with the *Titrant*. Perform the *Blank* determination.
Calculate the percentage of serine ($C_3H_7NO_3$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

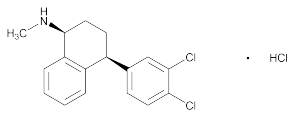
V_S = *Titrant* volume consumed by the *Sample* (mL)
V_B = *Titrant* volume consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F = equivalency factor, 105.1 mg/mEq
W = *Sample* weight (mg)
Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES
• **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%
• **CHLORIDE AND SULFATE,** *Chloride* ⟨**221**⟩
Standard solution: 0.50 mL of 0.020 N hydrochloric acid
Sample: 0.73 g of Serine
Acceptance criteria: NMT 0.05%
• **CHLORIDE AND SULFATE,** *Sulfate* ⟨**221**⟩
Standard solution: 0.10 mL of 0.020 N sulfuric acid
Sample: 0.33 g of Serine
Acceptance criteria: NMT 0.03%
• **IRON ⟨241⟩:** NMT 30 ppm
• **HEAVY METALS,** *Method I* ⟨**231**⟩**:** NMT 15 ppm
• **RELATED COMPOUNDS**
System suitability solution: 0.4 mg/mL each of USP L-Serine RS and USP L-Methionine RS in 0.1 N hydrochloric acid
Standard solution: 0.05 mg/mL of USP L-Serine RS in 0.1 N hydrochloric acid. [NOTE—This solution has a concentration equivalent to about 0.5% of that of the *Sample solution*.]
Sample solution: 10 mg/mL of Serine in 0.1 N hydrochloric acid
Chromatographic system
(See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)
Mode: TLC
Adsorbent: 0.25-mm layer of chromatographic silica gel mixture
Application volume: 5 µL
Developing solvent system: Butyl alcohol, glacial acetic acid, and water (3:1:1)
Spray reagent: 2 mg/mL of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5)
System suitability
Suitability requirements: The chromatogram of the *System suitability solution* exhibits two clearly separated spots.
Analysis
Samples: *System suitability solution*, *Standard solution*, and *Sample solution*.
After air-drying the plate, spray with *Spray reagent*, and heat between 100° and 105° for 15 min. Examine the plate under white light.
Acceptance criteria: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*.
Individual impurities: NMT 0.5%
Total impurities: NMT 2.0%

SPECIFIC TESTS
• **OPTICAL ROTATION,** *Specific Rotation* ⟨**781S**⟩
Sample solution: 100 mg/mL in 2 N hydrochloric acid
Acceptance criteria: +14.0° to +15.6°
• **LOSS ON DRYING ⟨731⟩:** Dry a sample at 105° for 3 h: it loses NMT 0.2% of its weight.

ADDITIONAL REQUIREMENTS
• **PACKAGING AND STORAGE:** Preserve in well-closed containers.
• **USP REFERENCE STANDARDS ⟨11⟩**
USP L-Methionine RS
USP L-Serine RS

Sertraline Hydrochloride



$C_{17}H_{17}Cl_2N \cdot HCl$ 342.69
1-Naphthalenamine, 4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-*N*-methyl-, hydrochloride, (1*S*-*cis*);
(1*S*,4*S*)-4-(3,4-Dichlorophenyl)-1,2,3,4-tetrahydro-*N*-methyl-1-naphthylamine hydrochloride [79559-97-0].

DEFINITION
Sertraline Hydrochloride contains NLT 97.0% and NMT 102.0% of $C_{17}H_{17}Cl_2N \cdot HCl$, calculated on the anhydrous basis.

IDENTIFICATION
• **A. INFRARED ABSORPTION ⟨197M⟩**
• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of sertraline hydrochloride from the *System suitability solution*, as obtained in the test for *Limit of (R,R) sertraline hydrochloride*.
• **C. IDENTIFICATION TESTS—GENERAL,** *Chloride* ⟨**191**⟩**:** Meets the requirements
Sample solution: A solution (1 in 10) in a mixture of alcohol and water (1:1)

ASSAY
• **PROCEDURE**
Buffer: 5.75 g/L of monobasic ammonium phosphate in water. Adjust with phosphoric acid to a pH 4.2.