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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 *Fluorescence Spectroscopy ⟨853⟩*.)

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

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SENNOSIDES TABLETS	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: Chromatographic Database

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