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Chondroitin Sulfate Sodium Tablets

DEFINITION

Chondroitin Sulfate Sodium Tablets contain NLT 90.0% and NMT 120.0% of the labeled amount of chondroitin sulfate sodium.

[NOTE—Chondroitin Sulfate Sodium is extremely hygroscopic once dried. Avoid exposure to the atmosphere, and weigh promptly.]

IDENTIFICATION

• A. ELECTROPHORESIS

Barium acetate buffer: Dissolve 25.24 g of barium acetate in 900 mL of water. Adjust with acetic acid to a pH of 5.0, and dilute with water to 1000 mL.

Staining reagent: 0.1% (w/v) toluidine blue in 0.1 M acetic acid

Standard solution: Use the *Standard solution* of middle concentration from the *Content of Chondroitin Sulfate Sodium*.

Sample solution: Prepare as directed in the *Content of Chondroitin Sulfate Sodium*.

Analysis: Fill the chambers of an electrophoresis apparatus suitable for separations on cellulose acetate membranes¹ (a small submarine gel chamber or one dedicated to membrane media) with *Barium acetate buffer*. Soak a cellulose acetate membrane 5–6 cm × 12–14 cm in *Barium acetate buffer* for 10 min, or until evenly wetted, then blot dry between two sheets of absorbent paper. Using an applicator² suitable for electrophoresis, apply equal volumes (0.5 µL) of the *Sample solution* and *Standard solution* to the brighter side of the membrane held in position in an appropriate applicator stand or on a separating bridge in the chamber. Ensure that both ends of the membrane are dipped at least 0.5–1.0-cm deep into the buffer chambers. Apply a constant 60 volts (6 mA at the start) for 2 h. [NOTE—Perform the application of solutions and voltage within 5 min because further drying of the blotted paper reduces sensitivity.]

Place the membrane in a plastic staining tray, and with the application side down, float or gently immerse in *Staining reagent* for 5 min. Then stir the solution gently for 1 min. Remove the membrane, and destain in 5% acetic acid until the background clears.

Acceptance criteria: The principal spot from the *Sample solution* has the same migration as the principal spot from the *Standard solution*.

[NOTE—Document the results by taking a picture within 15 min of completion of destaining.]

STRENGTH

• CONTENT OF CHONDROITIN SULFATE SODIUM

Standard solutions: 1.5, 1.0, and 0.5 mg/mL of [USP Chondroitin Sulfate Sodium RS](#) in water

Sample solution: Transfer an equivalent to 100 mg of chondroitin sulfate sodium from NLT 20 Tablets, finely powdered, to 60 mL of water, and shake to suspend the powder in solution. Sonicate in a 65° water bath for 20 min. Remove from the bath, stir or shake for 5 min, dilute with water to 100 mL, and centrifuge or pass through a suitable filter.

Diluent: Weigh about 297 mg of monobasic potassium phosphate, 492 mg of dibasic potassium phosphate, and 250 mg of polysorbate 80, and transfer into a 1-L beaker. Dissolve in approximately 900 mL of water, and adjust with potassium hydroxide or phosphoric acid to a pH of 7.0 ± 0.2. Dilute with water to 1 L, and mix thoroughly.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Photometric titration

Titrant: 1 mg/mL of cetylpyridinium chloride in water

Endpoint detection: Turbidimetric with photoelectric probe

Analysis: Transfer 5.0 mL of each *Standard solution* and the *Sample solution* to separate titration vessels, and add 25 mL of *Diluent* to each. Stir until a steady reading is obtained with a photoelectric probe either at 420, 550, or 660 nm. Set the instrument to zero in absorbance mode. Titrate with *Titrant* using the photoelectric probe to determine the endpoint turbidimetrically. From a linear regression equation, calculated using the volumes of *Titrant* consumed versus concentrations of the *Standard solutions*, determine the concentration of chondroitin sulfate sodium in the *Sample solution*.

Calculate the percentage of the labeled amount of chondroitin sulfate sodium in the portion of Tablets taken:

$$\text{Result} = (C/C_U) \times 100$$

C = determined concentration of chondroitin sulfate sodium in the *Sample solution* (mg/mL)

C_U = nominal concentration of chondroitin sulfate sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–120.0% of the label claim

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS \(2040\)](#): Meet the requirements for *Dissolution*

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Time: 60 min

Titrant and Diluent: Prepare as directed as in *Content of Chondroitin Sulfate Sodium*.

Standard solutions: 1.5, 1.0, and 0.5 mg/mL of [USP Chondroitin Sulfate Sodium RS](#) in water

Sample solution: Combine equal portions of the solutions withdrawn from 6 dissolution vessels and pass through a suitable filter; use the pooled sample as the test specimen.

Analysis: Transfer 5.0 mL of each *Standard solution*, and an aliquot of the *Sample solution* equivalent to about 5 mg of chondroitin sulfate sodium, to separate titration vessels. Add 25 mL of *Diluent* to each titration vessel. Stir until a steady reading is obtained with a photoelectric probe. Set the instrument to zero in absorbance mode. Titrate with *Titrant* using the photoelectric probe to determine the endpoint turbidimetrically, either at 420, 550, or 660 nm. From a linear regression equation, calculated using the volumes of *Titrant* consumed versus amount, in mg, of chondroitin sulfate sodium from each *Standard solution*, determine the amount, in mg, of chondroitin sulfate sodium in the aliquot of *Sample solution* taken.

Calculate the percentage of the labeled amount of chondroitin sulfate sodium dissolved:

$$\text{Result} = (Ws/a) \times (V/L) \times 100$$

Ws = amount of chondroitin sulfate sodium in the aliquot of the *Sample solution* taken (mg)

a = volume of the aliquot of *Sample solution* taken

V = volume of *Medium*, 900 mL

L = label claim of chondroitin sulfate sodium (mg/Tablet)

Tolerances: NLT 75% of the labeled amount of chondroitin sulfate sodium is dissolved.

- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and store at room temperature.
- **LABELING:** Label it to indicate the species of the source from which the chondroitin used to prepare the Tablets was derived. Label it to state the source(s) of chondroitin sulfate sodium, whether bovine, porcine, avian, or a mixture of any of them. The label states on the front panel the content of chondroitin sulfate sodium on the dried basis.
- [USP REFERENCE STANDARDS \(11\)](#).
[USP Chondroitin Sulfate Sodium RS](#)

¹ Suitable cellulose acetate membranes for electrophoresis are available from Fluka Chemical Corp., Milwaukee, WI; and DiaSys Corp., Waterbury, CT (www.diasys.com).

² Suitable applicators are available from DiaSys Corp., Waterbury, CT (www.diasys.com) and Helena Laboratories, Beaumont, TX (www.helena.com).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CHONDROITIN SULFATE SODIUM TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)