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Chondroitin Sulfate Sodium, Shark

Chondroitin, hydrogen sulfate, sodium salt

CAS RN®: 9082-07-9.

DEFINITION

Chondroitin Sulfate Sodium, Shark is the sodium salt of the sulfated linear glycosaminoglycan obtained from shark cartilages used for human foods. Chondroitin Sulfate Sodium, Shark consists mostly of the sodium salt of the sulfate ester of *N*-acetylchondrosamine (2-acetamido-2-deoxy-β-D-galactopyranose) and D-glucuronic acid copolymer. These hexoses are alternately linked β-1,4 and β-1,3 in the polymer.

Chondrosamine moieties in the prevalent glycosaminoglycan are monosulfated primarily on position 6 and less so on position 4 with minor disulfation on both positions 4 and 6. NLT 8% of the D-glucuronic acid moieties are monosulfated on position 2. It contains NLT 90.0% and NMT 105.0% of chondroitin sulfate sodium, calculated on the dried basis.

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

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), *Infrared Spectroscopy*:** 197K

• **B. IDENTIFICATION TESTS—GENERAL (191), *Chemical Identification Tests, Sodium***

Sample solution: 0.5 g in 10 mL of [water](#)

Acceptance criteria: Meets the requirements

• **C. SPECIFIC DISACCHARIDES:** The chromatogram of the enzymatically digested *Sample solution* as obtained in the test for *Disaccharide Composition* exhibits three main peaks due to 6-sulfated (ΔDi-6S), 4-sulfated (ΔDi-4S), and 2,6-disulfated (ΔDi-2,6diS) disaccharides, corresponding to those of the enzymatically digested *Standard solution*, with ΔDi-6S being the most abundant, followed by ΔDi-4S, and with NLT 8% corresponding to ΔDi-2,6diS. Additional minor peaks corresponding to nonsulfated (ΔDi-0S) and 4,6 disulfation may be detected.

Change to read:

• **D. SPECIFIC ROTATION:** Meets the requirements in the ▲*Optical Rotation* test. ▲ (USP 1-May-2024)

COMPOSITION

Change to read:

• **CONTENT OF CHONDROITIN SULFATE SODIUM**

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

Sample solution: Transfer 100 mg of dried Chondroitin Sulfate Sodium, Shark into a 100-mL volumetric flask, dissolve in 30 mL of [water](#), and dilute with [water](#) to volume.

Diluent: Weigh about 297 mg of [monobasic potassium phosphate](#), 492 mg of [dibasic potassium phosphate](#), and 250 mg of [polysorbate 80](#), and transfer to a 1-L beaker. Dissolve in 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](#). Degas before use.

Endpoint detection: Turbidimetric with a photoelectric probe

Analysis: Transfer 5.0 mL each of the *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 the photoelectric probe set at 420, 550, or 660 nm. Set the instrument to zero in absorbance mode ▲(if the option for zeroing is available). ▲ (USP 1-May-2024) 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 chondroitin sulfate sodium in the portion of Chondroitin Sulfate Sodium, Shark taken:

Result = $(C/C_U) \times 100$

C = concentration of chondroitin sulfate sodium in the aliquot of the *Sample solution*, obtained from the regression equation (mg/mL)

C_U = concentration of Chondroitin Sulfate Sodium, Shark in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–105.0% on the dried basis

Change to read:

• **DISACCHARIDE COMPOSITION**

Solution A: [Water](#) adjusted with 0.1 N [hydrochloric acid](#) to a pH of 3.5

Solution B: 1 M [sodium chloride](#) adjusted with 0.1 N [hydrochloric acid](#) to a pH of 3.5

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	100	0
4.0	100	0
45.0	50	50
45.1	100	0

Buffer solution: 50 mM [tris\(hydroxymethyl\)aminomethane](#) and 60 mM [sodium acetate](#), adjusted with diluted [hydrochloric acid](#) to a pH of 8.0

Standard solution: 2.4 mg/mL of dried [USP Chondroitin Sulfate Sodium, Shark RS](#) in [water](#)

Sample solution: Transfer about 250 mg of dried Chondroitin Sulfate Sodium, Shark to a 100-mL volumetric flask, and dissolve and dilute with [water](#) to volume. Filter to obtain a clear solution.

Blank: Water

Chondroitinase ABC solution: Dissolve 1 unit (U/mg of protein) of chondroitinase ABC¹ in 1.0 mL of *Buffer solution*. Mix thoroughly.

Chondroitinase ABC solution suitability: ▲ Dilute the incubated *Standard solution* and the incubated *Blank* (prepared in *Analysis*) separately in *Buffer solution* (1 in 10). Measure the absorbances of both solutions at 232 nm in 1-cm path cells (using 1- or 2-nm slit width) and make correction with the diluted incubated *Blank*.

Calculate the absorptivity of [USP Chondroitin Sulfate Sodium, Shark RS](#):

Result = $A/(C \times D \times d)$

A = absorbance of the diluted incubated *Standard solution*

C = concentration of [USP Chondroitin Sulfate Sodium, Shark RS](#) in the *Standard solution* (mg/mL)

D = dilution factor of the incubated *Standard solution*, 1/10

d = dilution factor for the UV measurement, 1/10

Chondroitinase ABC solution suitability requirement: The absorptivity of the incubated [USP Chondroitin Sulfate Sodium, Shark RS](#) is NLT 5

$\text{AU} \cdot \text{mL} \cdot \text{mg}^{-1} \cdot \text{cm}^{-1}$. ▲ (USP 1-May-2024)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 232 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L14](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: Incubated *Standard solution* (prepared in *Analysis*)

[NOTE—The relative retention times for the ΔDi-0S, ΔDi-6S, ΔDi-4S, and ΔDi-2,6diS peaks are 0.50, 0.75, 0.90, and 1.0, respectively.]