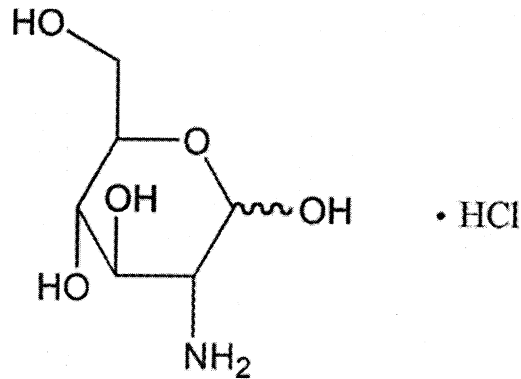


### Glucosamine Hydrochloride



$\text{C}_6\text{H}_{13}\text{NO}_5 \cdot \text{HCl}$  215.63


D-Glucose, 2-amino-2-deoxy-, hydrochloride.

2-Amino-2-deoxy- $\beta$ -D-glucopyranose hydrochloride [66-84-2].

» Glucosamine Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of  $\text{C}_6\text{H}_{13}\text{NO}_5 \cdot \text{HCl}$ , calculated on the dried basis.

**Packaging and storage**— Preserve in tight, light-resistant containers.

**USP Reference standards**  $\langle 11 \rangle$ —

USP Glucosamine Hydrochloride RS .

**Identification**—

**A:** *Infrared Absorption*  $\langle 197\text{K} \rangle$ .

**B:** It meets the requirements of the tests for *Chloride*  $\langle 191 \rangle$ .

**C:** 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.

**Specific rotation**  $\langle 781\text{S} \rangle$ : between  $+70.0^\circ$  and  $+73.0^\circ$ .

*Test solution*: 25 mg per mL.

**pH**  $\langle 791 \rangle$ : between 3.0 and 5.0, in a solution containing 20 mg per mL.

**Loss on drying**  $\langle 731 \rangle$ — Dry it at  $105^\circ$  for 2 hours: it loses not more than 1.0% of its weight.

**Residue on ignition**  $\langle 281 \rangle$ : not more than 0.1%.

**Sulfate**  $\langle 221 \rangle$ — A 0.10-g portion shows no more sulfate than corresponds to 0.25 mL of 0.020 N sulfuric acid: not more than 0.24% is found.

**Arsenic, Method II**  $\langle 211 \rangle$ : 3  $\mu\text{g}$  per g.

**Heavy metals, Method II**  $\langle 231 \rangle$ : 0.001%.

**Organic volatile impurities, Method I**  $\langle 467 \rangle$ : meets the requirements.

(Official until July 1, 2007)

**Assay—**

*Phosphate buffer*— Mix 1.0 mL of phosphoric acid with 2 L of water, and adjust with potassium hydroxide to a pH of 3.0.

*Mobile phase*— Prepare a mixture of *Phosphate buffer* and acetonitrile (3:2). Sonicate for 15 minutes, and pass through a filter having a 0.5- $\mu$ m or finer porosity. Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

*Standard preparation*— Dissolve an accurately weighed quantity of *USP Glucosamine Hydrochloride RS* in water to obtain a solution having a known concentration of about 1.0 mg per mL.

*Assay preparation*— Transfer about 100 mg of Glucosamine Hydrochloride, accurately weighed, to a 100-mL volumetric flask. Dissolve in 30 mL of water, shake by mechanical means, dilute with water to volume, and mix.

*Chromatographic system* (see *Chromatography* (621))— The liquid chromatograph is equipped with a 195-nm detector and a 4.6-mm  $\times$  25-cm column that contains packing L7. The flow rate is about 0.6 mL per minute. Chromatograph the *Standard preparation*, and record the responses as directed for *Procedure*: the tailing factor for the glucosamine peak 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  $\mu$ L) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the glucosamine peaks. Calculate the percentage of  $C_6H_{13}NO_5 \cdot HCl$  in the portion of Glucosamine Hydrochloride taken by the formula:

$$10,000(C/W)(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of *USP Glucosamine Hydrochloride RS* in the *Standard preparation*; *W* is the weight, in mg, of Glucosamine Hydrochloride used to prepare the *Assay preparation*; and  $r_U$  and  $r_S$  are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

**Auxiliary Information—** *Staff Liaison* : Lawrence Evans, III, Ph.D., Scientist

*Expert Committee* : (DSN05) Dietary Supplements - Non-Botanicals

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*Phone Number* : 1-301-816-8389