

## Glucosamine Hydrochloride

$C_6H_{13}NO_5$  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  $C_6H_{13}NO_5$  HCl, calculated on the dried basis.

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

### Identification—

A: Infrared Absorption 197K .

B: It meets the requirements of the tests for [Chloride](#) [191](#) .

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](#) [781S](#) : between  $+70.0^{\circ}C$  and  $+73.0^{\circ}C$

Test solution: 25 mg per mL, in water.

Measure the specific rotation 3 hours after sample preparation.

[pH](#) [791](#) : between 3.0 and 5.0, in a solution containing 20 mg per mL.

[Loss on drying](#) [731](#) — Dry it at  $105^{\circ}C$  or 2 hours: it loses not more than 1.0% of its weight.

[Residue on ignition](#) [281](#) : not more than 0.1%.

[Sulfate](#) [221](#) — 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](#) [211](#) : 3  $\mu$ g per g.

[Heavy metals, Method II](#) [231](#) : 0.001%.

### 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- $\mu\text{m}$  or finer porosity. Make adjustments if necessary.

**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**— 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  $\mu\text{L}$ ) 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  $\text{C}_6\text{H}_{13}\text{NO}_5 \cdot \text{HCl}$  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.