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Chlorothiazide Sodium for Injection

$C_7H_5ClN_3NaO_4S_2$ 317.71

2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-, 1,1-dioxide, monosodium salt.

6-Chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide monosodium salt CAS RN®: 7085-44-1; UNII: SN86FG7N2K.

» Chlorothiazide Sodium for Injection is a sterile, freeze-dried mixture of Chlorothiazide Sodium (prepared by the neutralization of Chlorothiazide with the aid of Sodium Hydroxide) and Mannitol. It contains chlorothiazide sodium ($C_7H_5ClN_3NaO_4S_2$) equivalent to not less than 93.0 percent and not more than 107.0 percent of the labeled amount of chlorothiazide ($C_7H_6ClN_3O_4S_2$).

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#), [Packaging for constitution](#).
USP REFERENCE STANDARDS (11)—

[USP Chlorothiazide RS](#)

Constituted solution—At the time of use, it meets the requirements for [Injections and Implanted Drug Products \(1\)](#), [Specific Tests, Completeness and clarity of solutions](#).

Change to read:

Identification, [▲Spectroscopic Identification Tests \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-May-2020) —

Solution: 10 µg per mL.

Medium: sodium hydroxide solution (1 in 250).

BACTERIAL ENDOTOXINS TEST (85) —It contains not more than 0.3 USP Endotoxin Unit per mg of chlorothiazide sodium.

UNIFORMITY OF DOSAGE UNITS (905): meets the requirements.

pH (791): between 9.2 and 10.0, in a solution prepared as directed in the labeling.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Transfer an accurately weighed portion of Chlorothiazide Sodium for Injection, equivalent to about 500 mg of chlorothiazide, to a 1000-mL volumetric flask, add sodium hydroxide solution (1 in 250) to volume, and mix. Transfer 5.0 mL of this solution to a 250-mL volumetric flask, dilute with sodium hydroxide solution (1 in 250) to volume, and mix. Concomitantly determine the absorbances of this solution and a Standard solution of [USP Chlorothiazide RS](#) in the same medium having a known concentration of about 10 µg per mL in 1-cm cells at the wavelength of maximum absorbance at about 292 nm, with a suitable spectrophotometer, using sodium hydroxide solution (1 in 250) as the blank. Calculate the quantity, in mg, of $C_7H_6ClN_3O_4S_2$ in the portion of Chlorothiazide Sodium for Injection taken by the formula:

$$50C(A_u/A_s)$$

in which C is the concentration, in µg per mL, of [USP Chlorothiazide RS](#) in the Standard solution; and A_u and A_s are the absorbances of the assay solution and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
CHLOROTHIAZIDE SODIUM FOR INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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