Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-4449241A-ABEE-4BE7-84D5-F11CF25F9B19_2_en-US
DOI: https://doi.org/10.31003/USPNF_M89665_02_01
DOI Ref: 6wd73

Zinc Gluconate Tablets

DEFINITION

Zinc Gluconate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of Zn, in the form of zinc gluconate ($C_{12}H_{22}O_{14}Zn$).

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Standard solution: USP Potassium Gluconate RS in water; 10 mg/mL

Sample solution: Transfer a weighed quantity of powdered Tablets to a suitable flask, and add the necessary volume of water to obtain a solution containing about 10 mg/mL of zinc gluconate. Shake and sonicate, heating in a water bath at 60°, if necessary, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 µL

Developing solvent system: Alcohol, water, ammonium hydroxide, and ethyl acetate (50:30:10:10)

Spray reagent: Dissolve 2.5 g of ammonium molybdate in about 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask, add 1.0 g of ceric sulfate, swirl to dissolve, dilute with 2 N sulfuric acid to volume, and mix.

Analysis

Samples: *Standard solution* and *Sample solution*

When the solvent front has moved about three-fourths the length of the plate, remove the plate from the chamber, and dry at 110° for 20 min. Allow to cool, spray with *Spray reagent*, and heat the plate at 110° for about 10 min.

Acceptance criteria: The principal spot from the *Sample solution* corresponds in color, size, and R_F value to that from the *Standard solution*.

• **B. Procedure**

Sodium hydroxide solution: 42 mg/mL of sodium hydroxide

Ammonium chloride solution: 107 mg/mL of ammonium chloride

Glycerin solution: A mixture of glycerin and water (85:15)

Sodium sulfide solution: Dissolve 12 g of sodium sulfide with heating in a 45-mL mixture of *Glycerin solution* and water (29:10), allow to cool, and dilute with the same mixture of solvents to 100 mL. The solution should be colorless.

Sample solution: Shake and sonicate the amount of powdered Tablets with the necessary volume of water to obtain a solution containing 100 mg/mL of zinc gluconate. Heat in a water bath at 60°, if necessary, and filter.

Analysis: To 5 mL of the *Sample solution* add 0.2 mL of *Sodium hydroxide solution*, add an additional 2 mL of *Sodium hydroxide solution*, and add 10 mL of *Ammonium chloride solution*. Add 0.1 mL of *Sodium sulfide solution*.

Acceptance criteria: A white precipitate is formed after the first addition of *Sodium hydroxide solution*. The precipitate dissolves after the second addition of *Sodium hydroxide solution*. The solution remains clear after addition of *Ammonium chloride solution*, and a white precipitate forms after addition of *Sodium sulfide solution*.

STRENGTH

• **Procedure**

Sample solution: Weigh and finely powder NLT 20 Tablets. Weigh a portion of the powder, equivalent to about 80 mg of zinc, transfer to a suitable crucible, and ignite, gently at first, until free from carbon. Cool the crucible, add 25 mL of water and 5 mL of hydrochloric acid, and stir. Heat on a steam bath for 5 min, and filter, rinsing the filter with several portions of water. Dilute the combined filtrate and washes with water to about 100 mL.

Analysis: Add ammonia–ammonium chloride buffer TS until the solution is neutral to litmus. Add 5 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 3.27 mg of Zn or 22.78 mg of zinc gluconate ($C_{12}H_{22}O_{14}Zn$).

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩:** For Tablets intended to be mixed with water prior to intake as oral liquids

Time: NMT 60 s

• **Disintegration and Dissolution of Dietary Supplements ⟨2040⟩:** For Tablets not to be mixed with water prior to ingestion

Medium: Hydrochloric acid 0.01 N; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Analysis: Determine the amount of $C_{12}H_{22}O_{14}Zn$ dissolved, employing atomic absorption spectrophotometry at the resonance emission line for zinc, at 213.8 nm, on filtered portions of the solution under test, suitably diluted with water, in comparison with a standard solution having a known concentration of zinc in the same *Medium*.

Tolerances: NLT 75% of the labeled amount of $C_{12}H_{22}O_{14}Zn$ is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and storage:** Preserve in tight containers, protected from light.

• **Labeling:** Label the Tablets in terms of elemental zinc, and also in terms of zinc gluconate ($C_{12}H_{22}O_{14}Zn$). The labeling indicates whether the Tablets are intended to be mixed with water before intake.

• **USP Reference Standards ⟨11⟩**

USP Potassium Gluconate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ZINC GLUCONATE TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 35(3)

Current DocID: GUID-4449241A-ABEE-4BE7-84D5-F11CF25F9B19_2_en-US
Previous DocID: GUID-4449241A-ABEE-4BE7-84D5-F11CF25F9B19_1_en-US
DOI: https://doi.org/10.31003/USPNF_M89665_02_01
DOI ref: 6wd73