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# Chlorothiazide Oral Suspension

**DEFINITION**  
Chlorothiazide Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of chlorothiazide (C<sub>7</sub>H<sub>6</sub>ClN<sub>3</sub>O<sub>4</sub>S<sub>2</sub>).

- IDENTIFICATION**
- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
  - **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

**ASSAY**

- **PROCEDURE**  
**Solution A:** 0.1% [formic acid](#) in water  
**Solution B:** [Methanol](#)  
**Mobile phase:** See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	94	6
4	94	6
14	80	20
18	40	60
25	40	60
26	94	6
30	94	6

**Diluent:** [Acetonitrile](#) and *Solution A* (30:70)  
**Standard solution:** 0.1 mg/mL of [USP Chlorothiazide RS](#) in *Diluent*  
**Sample stock solution:** 0.5 mg/mL of chlorothiazide in *Diluent* prepared as follows. Transfer a suitable amount of Oral Suspension, equivalent to 25 mg of chlorothiazide, to a 50-mL volumetric flask. Add 40 mL of *Diluent* and sonicate to dissolve. Dilute with *Diluent* to volume. Centrifuge and use the supernatant.  
**Sample solution:** Nominally 0.1 mg/mL of chlorothiazide in *Diluent*, from *Sample stock solution*  
**Chromatographic system**  
(See [Chromatography \(621\), System Suitability](#).)  
**Mode:** LC  
**Detector:** UV 275 nm. For *Identification test B*, use a diode array detector in the range of 200–400 nm.  
**Column:** 4.6-mm × 15-cm; 5-µm packing L1  
**Temperatures**  
**Autosampler:** 5°  
**Column:** 30°  
**Flow rate:** 1 mL/min

**Injection volume:** 10 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 1.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chlorothiazide ( $C_7H_6ClN_3O_4S_2$ ) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak response of chlorothiazide from the *Sample solution*

$r_S$  = peak response of chlorothiazide from the *Standard solution*

$C_S$  = concentration of [USP Chlorothiazide RS](#) in the *Standard solution* (mg/mL)

$C_U$  = nominal concentration of chlorothiazide in the *Sample solution* (mg/mL)

**Acceptance criteria:** 90.0%–110.0%

**PERFORMANCE TESTS**

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#)

**For single-unit containers**

**Acceptance criteria:** Meets the requirements

• [DELIVERABLE VOLUME \(698\)](#)

**For multiple-unit containers**

**Acceptance criteria:** Meets the requirements

**IMPURITIES**

• **ORGANIC IMPURITIES**

**Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system:** Proceed as directed in the Assay.

**Standard solution:** 10 µg/mL of [USP Benzothiadiazine Related Compound A RS](#) and 2 µg/mL of [USP Chlorothiazide RS](#) in *Diluent*

**Sample solution:** Nominally 1 mg/mL of chlorothiazide in *Diluent* prepared as follows. Transfer a suitable amount of Oral Suspension, equivalent to 25 mg of chlorothiazide, to a 25-mL volumetric flask. Add 20 mL of *Diluent* and sonicate to dissolve. Dilute with *Diluent* to volume. Centrifuge and use the supernatant.

**System suitability**

**Sample:** *Standard solution*

[NOTE—See [Table 2](#) for relative retention times.]

**Suitability requirements**

**Resolution:** NLT 4.0 between the benzothiadiazine related compound A and chlorothiazide peaks

**Relative standard deviation:** NMT 5.0% for chlorothiazide

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each individual unspecified degradation product in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak response of each unspecified degradation product from the *Sample solution*

$r_S$  = peak response of chlorothiazide from the *Standard solution*

$C_S$  = concentration of [USP Chlorothiazide RS](#) in the *Standard solution* (µg/mL)

$C_U$  = nominal concentration of chlorothiazide in the *Sample solution* (µg/mL)

**Acceptance criteria:** See [Table 2](#). Disregard any peak below 0.05%.

**Table 2**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Benzothiadiazine related compound A <sup>a</sup>	0.7	—
Chlorothiazide	1.0	—
Any individual unspecified degradation product	—	0.2
Total degradation products	—	2.0

<sup>a</sup> Not included in the total degradation products.

#### SPECIFIC TESTS

- [pH \(791\)](#): 3.2–4.0

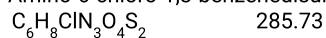
#### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. Protect from freezing and store at controlled room temperature.

- **USP REFERENCE STANDARDS (11).**

[USP Benzothiadiazine Related Compound A RS](#)

4-Amino-6-chloro-1,3-benzenedisulfonamide.



[USP Chlorothiazide RS](#)

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

Topic/Question	Contact	Expert Committee
CHLOROTHIAZIDE ORAL SUSPENSION	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2

**Chromatographic Database Information:** [Chromatographic Database](#)

#### Most Recently Appeared In:

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