

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jul-2023
Document Type: USP Monographs
DocId: GUID-0580EDEA-B8BB-449A-9BFC-5F9B938FB564_4_en-US
DOI: https://doi.org/10.31003/USPNF_M17092_04_01
DOI Ref: 3j085

© 2025 USPC
Do not distribute

Chlorzoxazone Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-clorzoxazone-tabs-20230630.

DEFINITION

Chlorzoxazone Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of chlorzoxazone ($C_7H_4ClNO_2$).

IDENTIFICATION

• A. ULTRAVIOLET ABSORPTION

Standard solution: 0.02 mg/mL of [USP Chlorzoxazone RS](#) in [methanol](#)

Sample stock solution: Nominally 1.0 mg/mL of chlorzoxazone from Tablets prepared as follows. Disperse a portion of powdered Tablets, equivalent to 100 mg of chlorzoxazone, in 100 mL of [methanol](#) and shake for 15 min. Pass the resulting solution through a suitable filter.

Sample solution: Nominally 0.02 mg/mL of chlorzoxazone from *Sample stock solution* in [methanol](#)

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*, concomitantly measured.

• B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Solution A: Dilute 10 mL of [glacial acetic acid](#) with [water](#) to make 1000 mL of solution.

Mobile phase: [Acetonitrile](#), [water](#), and [glacial acetic acid](#) (30:70:1)

Internal standard solution: 1.25 mg/mL of [phenacetin](#) in [acetonitrile](#)

Standard stock solution: 1.25 mg/mL of [USP Chlorzoxazone RS](#) in *Mobile phase*

Standard solution: 0.125 mg/mL of [USP Chlorzoxazone RS](#) from *Standard stock solution* and 0.25 mg/mL of [phenacetin](#) from *Internal standard solution* in *Solution A*

System suitability stock solution: 8.5 mg/mL of *p*-chlorophenol in [acetonitrile](#)

System suitability solution: 0.17 mg/mL of *p*-chlorophenol from *System suitability stock solution*, 0.1 mg/mL of [USP Chlorzoxazone RS](#) from *Standard stock solution*, and 0.25 mg/mL of [phenacetin](#) from *Internal standard solution* in *Solution A*

Sample stock solution: Nominally 1.25 mg/mL of chlorzoxazone prepared as follows. Finely powder Tablets (NLT 20) and transfer a portion of powder to an appropriate volumetric flask. Add 70% of the flask volume of [acetonitrile](#), and shake by mechanical means for about 30 min. Dilute with [acetonitrile](#) to volume. Filter a portion of this solution, discarding the first 10 mL of the filtrate.

Sample solution: Nominally 0.125 mg/mL of chlorzoxazone from *Sample stock solution* and 0.25 mg/mL of [phenacetin](#) from *Internal standard solution* in *Solution A*

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4-mm × 30-cm; packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—The relative retention times for phenacetin, chlorzoxazone, and *p*-chlorophenol are about 0.7, 1.0, and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between chlorzoxazone and *p*-chlorophenol, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chlorzoxazone ($C_7H_4ClNO_2$) in the portion of Tablets taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of chlorzoxazone to phenacetin from the *Sample solution*

R_S = peak response ratio of chlorzoxazone to phenacetin from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

[NOTE—Use 2-L vessels for this test.]

Medium: [pH 6.8 phosphate buffer](#); 1800 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: [USP Chlorzoxazone RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: 284 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of chlorzoxazone ($C_7H_4ClNO_2$) dissolved.

Tolerances: NLT 75% (Q) of the labeled amount of chlorzoxazone ($C_7H_4ClNO_2$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: [pH 6.8 phosphate buffer](#); 1800 mL

Apparatus 2: 75 rpm

Time: 90 min

Standard stock solution: 0.84 mg/mL of [USP Chlorzoxazone RS](#) in [methanol](#). Sonicate as necessary to dissolve.

Standard solution: 0.021 mg/mL of [USP Chlorzoxazone RS](#) from the *Standard stock solution* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 284 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chlorzoxazone ($C_7H_4ClNO_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of chlorzoxazone from the *Sample solution*

A_S = absorbance of chlorzoxazone from the *Standard solution*

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

V = volume of *Medium*, 1800 mL

D = dilution factor for the *Sample solution*