

Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-Aug-2022
 Document Type: USP Monographs
 DocId: GUID-5281EA4F-6E8D-4A64-991E-C43CA1500702_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M5213_04_01
 DOI Ref: o17o7

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Metaxalone Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-metaxalone-tabs-20220729>.

DEFINITION

Metaxalone Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of metaxalone ($C_{12}H_{15}NO_3$).

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.

ASSAY

• PROCEDURE

Buffer: 0.68 g/L of [monobasic potassium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 4.5.

Mobile phase: [Methanol](#) and *Buffer* (50:50)

Standard stock solution: 0.5 mg/mL of [USP Metaxalone RS](#) prepared as follows. Transfer a suitable amount of [USP Metaxalone RS](#) to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) and sonicate to dissolve. Dilute with *Buffer* to volume.

Standard solution: 0.05 mg/mL of [USP Metaxalone RS](#) from *Standard stock solution* in *Mobile phase*

Sample stock solution: Nominally 1.0 mg/mL of metaxalone from NLT 20 Tablets prepared as follows. Transfer a portion of finely powdered Tablets equivalent to NLT 500 mg of metaxalone to a suitable volumetric flask. Add 50% of the flask volume of [methanol](#) and sonicate for 10 min with occasional swirling. Shake on a mechanical shaker for 15 min. Add 40% of the flask volume of *Buffer* and allow the solution to cool to room temperature. Dilute with *Buffer* to volume. Pass a portion of the solution through a PVDF filter of 0.45- μ m pore size. Discard the first 5 mL. Use the filtrate.

Sample solution: Nominally 0.05 mg/mL of metaxalone from *Sample stock solution* and *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 226 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)

Column temperature: 50°

Flow rate: 1 mL/min

Injection volume: 20 μ L

Run time: NLT 2 times the retention time of metaxalone

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of metaxalone ($C_{12}H_{15}NO_3$) in the portion of Tablets taken:

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

r_U = peak response of metaxalone from the *Sample solution*

r_S = peak response of metaxalone from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS**Change to read:**

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

Test 1

Medium: 0.5% sodium lauryl sulfate; 900 mL

Apparatus 2: 100 rpm

Time: 60 min

Buffer, Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay, except use 270 nm for analysis.

Standard solution: ($L/900$) mg/mL of [USP Metaxalone RS](#), where L is the label claim of metaxalone, in mg/Tablet, prepared as follows.

Transfer a suitable quantity of [USP Metaxalone RS](#) to a suitable volumetric flask. Add 4% of the flask volume of [methanol](#), sonicate to dissolve, and dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable PVDF membrane filter of 0.45- μ m pore size. Discard the first 5 mL of the filtrate and use the remaining amount for analysis.

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of metaxalone ($C_{12}H_{15}NO_3$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of the *Medium*, 900 mL

L = label claim of metaxalone (mg/Tablet)

Tolerances: NLT 60% (Q) of the labeled amount of metaxalone ($C_{12}H_{15}NO_3$) is dissolved.

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

Medium: 5 g/L of [sodium dodecyl sulfate](#) in [water](#), deaerated; 900 mL

Apparatus 2: 100 rpm

Time: 120 min

Standard solution: ($L/900$) mg/mL of [USP Metaxalone RS](#), where L is the label claim of metaxalone in mg/Tablet, prepared as follows.

Transfer a suitable quantity of [USP Metaxalone RS](#) to a suitable volumetric flask. Add 5% of the flask volume of [methanol](#), sonicate to dissolve, and dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 272 nm

Cell: 0.2 cm

Blank: *Medium*

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of metaxalone ($C_{12}H_{15}NO_3$) dissolved:

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

A_U = absorbance of metaxalone from the *Sample solution*

A_S = absorbance of metaxalone from the *Standard solution*

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

V = volume of the *Medium*, 900 mL

L = label claim of metaxalone (mg/Tablet)

Tolerances: NLT 70% (Q) of the labeled amount of metaxalone ($C_{12}H_{15}NO_3$) is dissolved.