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## Metoclopramide Tablets

### DEFINITION

Metoclopramide Tablets contain an amount of metoclopramide hydrochloride ( $C_{14}H_{22}ClN_3O_2 \cdot HCl \cdot H_2O$ ) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of metoclopramide ( $C_{14}H_{22}ClN_3O_2$ ).

### 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

**Mobile phase:** Dissolve 2.7 g of sodium acetate in 500 mL of water. Add 500 mL of acetonitrile and 2 mL of tetramethylammonium hydroxide solution in methanol (1 in 5), and mix. Adjust with glacial acetic acid to a pH of 6.5, filter, and degas.

**System suitability stock solution:** Transfer 12.5 mg of benzenesulfonamide to a 25-mL volumetric flask. Add 15 mL of methanol, and shake to dissolve. Dilute with 0.01 M phosphoric acid to volume.

**Standard stock solution:** 0.9 mg/mL of [USP Metoclopramide Hydrochloride RS](#) in 0.01 M phosphoric acid

**System suitability solution:** Transfer 5 mL of *System suitability stock solution* and 5 mL of *Standard stock solution* into a 100-mL volumetric flask, and dilute with 0.01 M phosphoric acid to volume.

**Standard solution:** 45  $\mu$ g/mL of [USP Metoclopramide Hydrochloride RS](#) (equivalent to 40  $\mu$ g/mL of metoclopramide) from *Standard stock solution* diluted with 0.01 M phosphoric acid

**Sample solution:** Nominally 40  $\mu$ g/mL of metoclopramide, prepared as follows. Weigh and finely powder NLT 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 40 mg of metoclopramide, to a 100-mL volumetric flask, add about 70 mL of 0.01 M phosphoric acid, and sonicate for 5 min. Cool to room temperature, dilute with 0.01 M phosphoric acid to volume, and mix. Pass the solution through a filter of 0.45- $\mu$ m pore size, discarding the first portion of the filtrate. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, and dilute with 0.01 M phosphoric acid to volume.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 215 nm or diode array. [NOTE—Use the diode array detector to perform *Identification test B.*]

**Column:** 4.6-mm  $\times$  25-cm; packing L1

**Flow rate:** 1.5 mL/min

**Injection volume:** 20  $\mu$ L

#### System suitability

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

#### Suitability requirements

[NOTE—The relative retention times for benzenesulfonamide and metoclopramide are 0.7 and 1.0, respectively.]

**Resolution:** NLT 1.5 between the benzenesulfonamide and metoclopramide peaks, *System suitability solution*

**Tailing factor:** NMT 2.0 for the metoclopramide peak, *Standard solution*

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

#### Analysis

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

Calculate the percentage of the labeled amount of metoclopramide ( $C_{14}H_{22}ClN_3O_2$ ) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

$r_s$  = peak response from the *Standard solution*

$C_s$  = concentration of [USP Metoclopramide Hydrochloride RS](#) in the *Standard solution* ( $\mu\text{g/mL}$ )

$C_u$  = nominal concentration of metoclopramide in the *Sample solution* ( $\mu\text{g/mL}$ )

$M_{r1}$  = molecular weight of metoclopramide, 299.80

$M_{r2}$  = molecular weight of anhydrous metoclopramide hydrochloride, 336.26

**Acceptance criteria:** 90.0%–110.0%

## PERFORMANCE TESTS

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

**Medium:** Water; 900 mL

**Apparatus 1:** 50 rpm

**Time:** 30 min

**Standard solution:** [USP Metoclopramide Hydrochloride RS](#) at a known concentration in *Medium*

**Sample solution:** Filtered portion of the solution under test, suitably diluted with *Medium*

### Instrumental conditions

**Mode:** UV-Vis

**Analytical wavelength:** Wavelength of maximum absorbance at about 309 nm

**Tolerances:** NLT 75% ( $Q$ ) of the labeled amount of metoclopramide ( $\text{C}_{14}\text{H}_{22}\text{ClN}_3\text{O}_2$ ) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

## IMPURITIES

- [ORGANIC IMPURITIES](#)

**Mobile phase:** Prepare a 1.88 g/L solution of sodium 1-hexanesulfonate solution (0.01 M solution) in a mixture of acetonitrile and water (60:40), and adjust with glacial acetic acid to a pH of 4.0.

**Standard solution:** 5.5  $\mu\text{g/mL}$  of [USP Metoclopramide Hydrochloride RS](#) in *Mobile phase*

**Sample solution:** Shake a quantity of the powdered Tablets containing the equivalent of 100 mg of metoclopramide with 20 mL of methanol for 5 min, and pass through a suitable filter, discarding the first few mL of the filtrate. Dilute a portion of the filtrate with *Mobile phase* to obtain a solution containing about 1.0  $\mu\text{g/mL}$  of metoclopramide.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 265 nm

**Column:** 4.6-mm  $\times$  25-cm; 5- $\mu\text{m}$  packing L1

**Flow rate:** 2 mL/min

**Injection volume:** 20  $\mu\text{L}$

### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Tailing factor:** NMT 1.8

**Relative standard deviation:** NMT 5.0%

### Analysis

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

Calculate the percentage of any individual impurity in the portion of Tablets taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (M_{r1}/M_{r2}) \times 100$$

$r_u$  = peak response of each impurity from the *Sample solution*

$r_s$  = peak response of metoclopramide from the *Standard solution*

$C_s$  = concentration of [USP Metoclopramide Hydrochloride RS](#) in the *Standard solution* ( $\mu\text{g/mL}$ )

$C_u$  = nominal concentration of metoclopramide in the *Sample solution* ( $\mu\text{g/mL}$ )

$M_{r1}$  = molecular weight of metoclopramide, 299.80 $M_{r2}$  = molecular weight of anhydrous metoclopramide hydrochloride, 336.26**Acceptance criteria:** NMT 0.5% of any individual impurity is found.**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at controlled room temperature.
- **USP REFERENCE STANDARDS (11):**  
[USP Metoclopramide Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
METOCLOPRAMIDE TABLETS	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)**Most Recently Appeared In:**

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