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## Metoclopramide Tablets

### [General Notices](#)

Details for the public consultation of this monograph are as follows:

EAG/Panel/Working Party	Medicinal Chemicals 2
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Deadline for Comment	30 <sup>th</sup> September 2026
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Notes	<p>Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. <b>Identification</b> Test revised to be harmonised with Assay. <b>Related substances</b> Test revised improved with methodology. <b>Assay</b> LC method harmonised with new related substances test <b>Impurities</b> section added</p>

### Action and use

Dopamine receptor antagonist; antiemetic.

### DEFINITION

Metoclopramide Tablets contain [Metoclopramide Hydrochloride Monohydrate](#).

The tablets comply with the requirements stated under [Tablets](#) and with the following requirements.

### Content of anhydrous metoclopramide hydrochloride, $C_{14}H_{22}ClN_3O_2 \cdot HCl$

95.0 to 105.0% of the stated amount.

### IDENTIFICATION

A. In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 200 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

B. Yields the reactions characteristic of chlorides, [Appendix VI](#).

## TESTS

### Dissolution

Comply with the [dissolution test for tablets and capsules, Appendix XII B1](#).

#### TEST CONDITIONS

- Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
- Use 900 mL of 0.1M [hydrochloric acid](#), at a temperature of 37°, as the medium.

#### PROCEDURE

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions.

- After 30 minutes withdraw a sample of the medium and filter (a 0.45-µm nylon filter is suitable). Use the filtered medium, diluted, if necessary, to produce a solution expected to contain 0.00059% w/v of anhydrous metoclopramide hydrochloride.
- 0.00056% w/v of [metoclopramide hydrochloride BPCRS](#) in dissolution medium.

#### CHROMATOGRAPHIC CONDITIONS

- Use a stainless steel column (25 cm × 4.6 mm) packed with [octylsilyl silica gel for chromatography](#) (5 µm) (Luna C8 is suitable).
- Use isocratic elution and the mobile phase described below.
- Use a flow rate of 1.5 mL per minute.
- Use an ambient column temperature.
- Use a detection wavelength of 240 nm.
- Inject 20 µL of each solution.

#### MOBILE PHASE

**Solution A** 0.02% v/v of [N,N-dimethyloctylamine](#) in 0.68% w/v of [potassium dihydrogen orthophosphate](#). Adjust the pH of the mixture to pH 4.0 with 10% [orthophosphoric acid](#).

**Mobile phase** 17 volumes of [acetonitrile](#) and 83 volumes of Solution A.

#### DETERMINATION OF CONTENT

Calculate the total content of anhydrous metoclopramide hydrochloride,  $C_{14}H_{22}ClN_3O_2 \cdot HCl$ , in the medium from the chromatograms obtained and using the declared content of  $C_{14}H_{22}ClN_3O_2 \cdot HCl$  in [metoclopramide hydrochloride BPCRS](#).

#### LIMITS

The amount of anhydrous metoclopramide hydrochloride released is not less than 80% (Q) of the stated amount.

#### Related substances

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions prepared in [water](#).

- (1) Disperse a quantity of the powdered tablets in [water](#) to produce a solution equivalent to 0.1% w/v of anhydrous metoclopramide hydrochloride and filter (a 0.45- $\mu$ m nylon filter is suitable).
- (2) Dilute 1 volume of solution (1) to 200 volumes.
- (3) 0.001% w/v of [metoclopramide hydrochloride BPCRS](#) and 0.001% w/v of [metoclopramide impurity A EPCRS](#).
- (4) Dilute 1 volume of solution (2) to 5 volumes.

#### CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Dissolution can be used, excluding the (f). Inject 5  $\mu$ L of each solution.

Allow the chromatography to proceed for 10 times the retention time of metoclopramide.

#### SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to impurity A and metoclopramide is at least 2.0.

#### CALCULATION OF IMPURITIES

For each impurity, use the concentration of anhydrous metoclopramide hydrochloride in solution (2).

For the reporting threshold, use the concentration of anhydrous metoclopramide hydrochloride in solution (4).

For peak identification, use solution (3).

Metoclopramide retention time: about 5 minutes.

Relative retentions: impurity A, about 0.8; impurity F, about 0.85; impurity H, about 0.9; impurity G, about 1.3; impurity C, about 3.0; impurity D, about 3.2 and impurity B, about 8.0.

#### LIMITS

— unspecified impurities: for each impurity, not more than 0.2%;

- total impurities: not more than 0.5%;
- reporting threshold: 0.1%.

## ASSAY

Weigh and powder 20 tablets. Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions prepared in 0.1 M [hydrochloric acid](#).

- (1) Disperse a quantity of the powdered tablets to produce a solution equivalent to 0.1% w/v of anhydrous metoclopramide hydrochloride and filter (a 0.45- $\mu$ m nylon filter is suitable).
- (2) 0.105% w/v of [metoclopramide hydrochloride BPCRS](#).

### CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Dissolution can be used.

### DETERMINATION OF CONTENT

Calculate the content of  $C_{14}H_{22}ClN_3O_2$ , HCl, in the tablets from the chromatograms obtained and using the declared content of  $C_{14}H_{22}ClN_3O_2$ , HCl in [metoclopramide hydrochloride BPCRS](#).

## STORAGE

Metoclopramide Tablets should be protected from light.

## LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of anhydrous metoclopramide hydrochloride.

## IMPURITIES

The impurities limited by the requirements of this monograph include impurities A, B, C, D, F, G and H listed under [Metoclopramide Hydrochloride Monohydrate](#).