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Metoclopramide Oral Solution

General Notices

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

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Deadline for Comment	30th September 2026
Target Publication Date (subject to change)	BP 2028
Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. **Identification** Test revised improved with methodology. **Assay** Test revised improved with methodology. **Impurities** section added

Action and use

Dopamine receptor antagonist; antiemetic.

DEFINITION

Metoclopramide Oral Solution is a solution of Metoclopramide Hydrochloride Monohydrate in a suitable vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements.

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

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

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Mix a quantity of the oral solution containing the equivalent of 2 mg of anhydrous metoclopramide hydrochloride with sufficient of the mobile phase to produce 10 mL and filter (Whatman GF/C filter paper is suitable).
(2) Dilute 1 volume of solution (1) to 200 volumes with the mobile phase.
(3) 0.0001% w/v of *metoclopramide hydrochloride BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (10 µm) (Spherisorb ODS 1 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 265 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

0.01M *sodium hexanesulfonate* in a mixture of 40 volumes of *water* and 60 volumes of *acetonitrile*. Adjust the mixture to pH 4.0 with *glacial acetic acid*.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%).

Disregard any peaks with a retention time relative to the principal peak of 0.5 or less.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in *water*.

(1) Dilute a weighed amount of the oral solution to produce a solution equivalent to 0.1% w/v of anhydrous metoclopramide hydrochloride.
(2) 0.105% w/v of *metoclopramide hydrochloride BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octylsilyl silica gel for chromatography* (5 µm) (Luna C8 is suitable).
(b) Use elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 240 nm.
(f) Inject 5 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 A 17 volumes of *acetonitrile* and 83 volumes of Solution A.

Mobile phase B 40 volumes of Solution A and 60 volumes of *acetonitrile*.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-18	100	0	isocratic
18-23	100→0	0→100	linear gradient
23-35	0	100	isocratic
35-40	0→100	100→0	linear gradient
40-60	100	0	re-equilibration

When the chromatograms are recorded under the prescribed conditions, the retention time of anhydrous metoclopramide is about 5 minutes.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the oral solution, Appendix V G, and calculate the content of $C_{14}H_{22}ClN_3O_2$,HCl, weight in volume, using the declared content of $C_{14}H_{22}ClN_3O_2$,HCl in *metoclopramide hydrochloride BPCRS*.

STORAGE

Metoclopramide Oral Solution 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 those listed under Metoclopramide Hydrochloride Monohydrate.