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Metoclopramide Injection

General Notices

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

EAG/Panel/Working Party	Medicinal Chemicals 2
Contact Details	helen.corns@mhra.gov.uk rachael.feltham@mhra.gov.uk sophie.cherrington@mhra.gov.uk bpcom@mhra.gov.uk
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Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. **Identification** Test revised to be harmonised with Assay. **Related substances** Test revised improved with methodology. **Assay** LC method harmonised with new related substances test **Impurities** section added

Action and use

Dopamine receptor antagonist; antiemetic.

DEFINITION

Metoclopramide Injection is a sterile solution of Metoclopramide Hydrochloride Monohydrate in a suitable vehicle.

The injection complies with the requirements stated under Parenteral Preparations 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 prepared in *water*.

(1) Dilute the injection, if necessary, to produce a solution equivalent to 0.1% w/v of anhydrous metoclopramide hydrochloride.
(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

(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 isocratic 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 17 volumes of *acetonitrile* and 83 volumes of Solution A.

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 hydrochloride 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

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

(1) Dilute a weighed amount of the injection 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

The chromatographic conditions described under Related substances should be used.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the injection, 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 Injection should be protected from light.

LABELLING

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

LABELLING

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A, B, C, D, F, G and H listed under Metoclopramide Hydrochloride Monohyrdate.