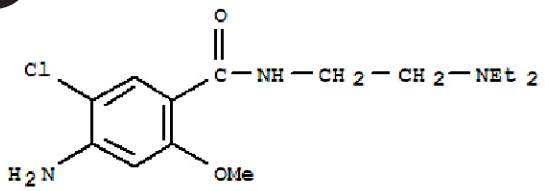
Taj Pharmaceuticals Ltd.

Metoclopramide Hydrochloride
CAS No. 54143-57-6



Metoclopramide Hydrochloride
Metoclopramide Hydrochloride Monohydrate USP

Specification: IP /BP/ USP

Chemical name:
4-amino-5-chloro-N-[2-(diethylamino)ethyl]-
2-methoxybenzamide hydrochloride

- HCl

Molecular formula: C14H23Cl2N3O2, H2O
Molecular weight: 354.3
CAS Registery number: 54143-57-6

- H2O

General information:
White or practically white, crystalline, odorless or practically odorless powder. Very soluble in water; freely soluble in alcohol; sparingly soluble in chloroform; practically insoluble in ether.

Content of metoclopramide hydrochloride
calculated on anhydrous substance: 98.0% - 101.0% (USP)
Action and use

Dopamine receptor antagonist; antiemetic.

Preparations

Metoclopramide Injection
Metoclopramide Oral Solution
Metoclopramide Tablets

DEFINITION

Metoclopramide hydrochloride contains not less than 99.0 per cent and not more than the equivalent of 101.0 per cent of **4-amino-5-chloro- N-[2-(diethylamino)ethyl]-2-** methoxybenzamide hydrochloride, calculated with reference to the anhydrous substance.

CHARACTERS: White or almost white, crystalline powder or crystals, very soluble in water, freely soluble in alcohol, sparingly soluble in methylene chloride. It melts at about 183 °C with decomposition.

DENTIFICATION

First identificationiA, B, D.
Second identificationiA, C, D, E.
iA. The pH (2.2.3) of solution S (see Tests) is 4.5 to 6.0.

iB. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the spectrum obtained with metoclopramide hydrochloride CRS. Examine the substances as discs prepared using potassium chloride R.

TAJ PHARMACEUTICALS LIMITED. (API)

Metoclopramide Hydrochloride

I.P/B.P U.S.P

CAS NO:54143-57-6

Molecular formula: $C_{14}H_{23}Cl_2N_3O_2, H_2O$

ıC. Examine the chromatograms obtained in the test for related substances in ultraviolet light before spraying with dimethylaminobenzaldehyde solution R1**.** The principal spot in the chromatogram obtained with test solution **(**b**)** is similar in position and size to the principal spot in the chromatogram obtained with reference solution **(**a**).**

ıD. Dilute 1 ml of solution S to 2 ml with water R**.** The solution gives reaction **(**a**)** of chlorides **(**2**.**3**.**1**).**

ıE. Dissolve about 2 mg in 2 ml aromatic amines **(**2**.**3**.**1**).**

TESTS

Solution S : Dissolve 2.5 g in carbon dioxide-free water R and dilute to 25 ml with the same solvent.

Appearance of solution : Solution S is clear (2.2.1) and colourless (2.2.2, Method II).

Related substances: Examine by thin-layer chromatography (2.2.27), using silica gel HF254 R as the coating substance.

Test solution (a)iDissolve 0.40 g of the substance to be examined in methanol R and dilute to 10 ml with the same solvent.

Test solution (b)iDilute 1 ml of test solution (a) to 10 ml with methanol R. Reference solution (aiDissolve 20 mg of metoclopramide hydrochloride CRS in methanol R and dilute to 5 ml with the same solvent.

Reference solution (b)iDilute 5 ml of test solution (a) to 100 ml with methanol R. Dilute 1 ml of this solution to 10 ml with methanol R. Reference solution (c)iDissolve 10 mg of N,N-diethylethylenediamine R in methanol R and dilute to 50 ml with the same solvent.

Apply separately to the plate 5 µl of each solution. Develop over a path of 12 cm using a mixture of 2 volumes of concentrated ammonia R, 10 volumes of dioxan R, 14 volumes of methanol R and 90 volumes of methylene chloride R. Allow the plate to dry in air. Examine in ultraviolet light at 254 nm. Any spot in the chromatogram obtained with test solution (a), apart from the principal spot, is not more intense than the spot in the chromatogram obtained with reference solution (b) (0.5 per cent). Spray with dimethylaminobenzaldehyde solution R1.

Allow the plate to dry in air. Any spot in the chromatogram obtained with test solution (a) that has not been visualised in ultraviolet light at 254 nm is not more intense than the spot in the chromatogram obtained with reference solution (c) (0.5 per cent).

Heavy metals (2.4.8) 12 ml of solution S complies with limit test A for heavy metals (20 ppm). Prepare the standard

using lead standard solution (2 ppm Pb) R. 4.5 per cent to 5.5 per cent, determined on 0.500 g by the semi-micro determination of water.

ASSAY

Dissolve 0.2500 g in a mixture of 5.0 ml of 0.01 M hydrochloric acid and 50 ml of alcohol R. Carry out a potentiometric titration (2.2.20), using 0.1 M sodium hydroxide. Read the volume of 0.1 M sodium hydroxide added between the two points of inflexion.

1 ml of 0.1 M sodium hydroxide is equivalent to 33.63 mg of C14H23Cl2N3O2.

STORAGE

Store protected from light.

PACKAGE: 25kg/ Drum

Note: **** These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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