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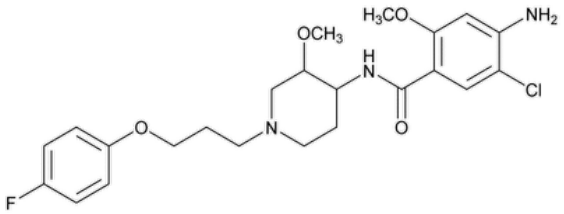
Cisapride



$C_{23}H_{29}ClFN_3O_4$ 465.95

Benzamide, 4-amino-5-chloro-*N*-[1-[3-(4-fluorophen oxy)propyl]-3-methoxy-4-piperidinyl]-2-methoxy-, *cis*-.

cis-4-Amino-5-chloro-*N*-[1-[3-(*p*-fluorophenoxy)propyl]-3-methoxy-4-piperidyl]-*o*-anisamide CAS RN®: 81098-60-4; UNII: UVL329170W.

Monohydrate 484.0 CAS RN®: 260779-88-2; UNII: VZV0A4I38W.

» Cisapride contains not less than 99.0 percent and not more than 101.0 percent of $C_{23}H_{29}ClFN_3O_4$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed, light- resistant containers, and store at room temperature.

USP Reference Standards ⟨11⟩—

USP Cisapride RS
USP Haloperidol RS

Completeness of Solution ⟨641⟩—A solution, 10 mg per mL in methylene chloride, meets the requirements.

Change to read:

Identification, ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Specific Rotation ⟨781S⟩**:** between −10° and +10°, measured at 20°.

Test solution: 10 mg per mL, in methylene chloride.

Water Determination, *Method I* ⟨921⟩ **:** between 3.4% and 4.0%.

Residue on Ignition ⟨281⟩**:** not more than 0.1%.

Chromatographic purity—

Solution A—Prepare a 20 g per L solution of tetrabutylammonium hydrogen sulfate in water.

Solution B—Use methanol.

Mobile phase—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Blank solution—Use methanol.

System suitability solution—Prepare a solution of USP Cisapride RS and USP Haloperidol RS in methanol containing about 0.05 mg per mL and 0.4 mg per mL, respectively.

Test solution 1—Dissolve an accurately weighed quantity of Cisapride, in methanol to obtain a solution having a known concentration of about 10 mg per mL.

Test solution 2—Dilute quantitatively and stepwise *Test solution 1* in methanol to obtain a solution having a known concentration of about 0.05 mg per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 275-nm detector and a 4.0-mm × 10-cm column that contains 3-µm base-deactivated packing L1. The flow rate is about 1.2 mL per minute. The chromatograph is programmed as follows.

Time (minutes)	*Solution A* (%)	*Solution B* (%)	Elution
0–20	80→55	20→45	linear gradient

Time (minutes)	*Solution A* (%)	*Solution B* (%)	Elution
20–21	55→5	45→95	linear gradient
21–25	5	95	isocratic
25–26	5→80	95→20	return to initial conditions
26–30	80	20	re-equilibration

Chromatograph the *System suitability solution,* and record the peak responses as directed for *Procedure:* the order of elution is cisapride followed by haloperidol, the resolution, *R,* between these two peaks is not less than 2.5; and the relative standard deviation for replicate injections is not more than 2.0% for the cisapride peak.

Procedure—Inject a volume (about 10 µL) of the *Blank solution, Test solution 1,* and *Test solution 2* into the chromatograph, record the chromatograms, and measure the peak areas. Calculate the percentage of cisapride impurities in the portion of Cisapride taken by the formula:

$$100(C_S/C_i)(r_i/r_S)$$

in which C_S and C_i are the concentration of cisapride, in mg per mL, of *Test solution 2* and *Test solution 1,* respectively; r_i is the individual peak response of cisapride inpurities in *Test solution 1;* and r_S is cisapride peak area in *Test solution 2:* not more than 0.5% of any cisapride impurity is found, and not more than 1.0% of total impurities is found. Disregard any peak also found in the *Blank solution* and any peak with an area less than 0.1 times the area of the principal peak in the *Test solution 2* chromatogram.

Assay—Dissolve about 0.350 g of Cisapride, accurately weighed, in 70 mL of a mixture of methyl ethyl ketone and acetic acid (7:1). Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N perchloric acid is equivalent to 46.60 mg of $C_{23}H_{29}ClFN_3O_4$.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CISAPRIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 34(2)

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