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Omeprazole Oral Suspension

General Notices

NOTE: *This monograph has been developed to cover unlicensed formulations.*

Action and use

Proton pump inhibitor; treatment of peptic ulcer disease.

DEFINITION

Omeprazole Oral Suspension is a suspension containing Omeprazole in a suitable alkaline vehicle.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral suspension also complies with the requirements stated under Unlicensed Medicines.

Content of omeprazole, $C_{17}H_{19}N_3O_3S$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Disperse a volume of the oral suspension containing 2 mg of Omeprazole in 0.1M *sodium hydroxide* and dilute to 100 mL with the same solution. Mix with the aid of ultrasound for 10 minutes and filter the resulting suspension. The *light absorption*, Appendix II B, in the range 230 to 350 nm exhibits absorption maxima at 276 nm and at 305 nm.
B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).

TESTS

Dissolution

The requirement stated under Unlicensed Medicines, Oral Suspensions does not apply to Omeprazole Oral Suspension.

Buffer capacity

Not less than 400, when determined by the following method.

Measure the pH of 30 mL of the oral suspension, Appendix V L. Add sufficient 0.5M *hydrochloric acid* to change the initial pH by 1 unit. Calculate the buffer capacity (β) [the amount of strong acid or base that must be added to 1 litre of the solution to change the pH by one unit] using the following expression:

$$\beta = V_A \times 1000 / V_S \times C$$

where,

V_A = the volume of 0.5M *hydrochloric acid* required to change the pH by 1 unit (in mL),

V_S = the volume of oral suspension (in mL),

C = the concentration of 0.5M *hydrochloric acid* (in moles per litre).

Related substances

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

(1) Disperse a quantity of the oral suspension containing 24 mg of Omeprazole in 150 mL of mobile phase, mix with the aid of ultrasound for 30 minutes, dilute with sufficient mobile phase to produce 200 mL, mix and filter.
(2) Dilute 1 volume of solution (1) to 20 volumes with the mobile phase. Dilute 1 volume of this solution to 10 volumes with the mobile phase.
(3) Mix 10 mg of each of *omeprazole BPCRS* and *omeprazole impurity D EPCRS* in the mobile phase and dilute to 100 mL with the same solvent.
(4) Dilute 1 volume of solution (2) to 10 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octylsilyl silica gel for chromatography* (5 µm) (Nucleosil RP8 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 280 nm.
(f) Inject 40 µL of each solution.
(g) For solution (1), allow the chromatography to proceed for 3 times the retention time of omeprazole.

MOBILE PHASE

27 volumes of *acetonitrile* and 73 volumes of a 0.14% w/v solution of *disodium hydrogen orthophosphate* previously adjusted to pH 7.6 with *orthophosphoric acid*.

When the chromatograms are recorded under the prescribed conditions the retention time of omeprazole is about 9 minutes.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity D and omeprazole is at least 3.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak due to impurity D is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

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

the sum of the areas of any *secondary peaks* is not greater than four times the area of the principal peak in the chromatogram obtained with solution (2) (2.0%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.05%).

ASSAY

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

(1) Disperse a weighed quantity of the oral suspension containing 24 mg of Omeprazole in 150 mL of mobile phase, mix with the aid of ultrasound for 30 minutes, dilute with sufficient mobile phase to produce 200 mL, mix and filter. Dilute 1 volume of the resulting solution to 10 volumes with the mobile phase.
(2) 0.0012% w/v of *omeprazole BPCRS* in the mobile phase.
(3) Mix 10 mg of each of *omeprazole BPCRS* and *omeprazole impurity D EPCRS* in the mobile phase and dilute to 100 mL with the same solvent.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used but using a detection wavelength of 305 nm.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity D and omeprazole is at least 3.0.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_{17}H_{19}N_3O_3S$, weight in volume, from the chromatograms obtained and using the declared content of $C_{17}H_{19}N_3O_3S$ in *omeprazole BPCRS*.

STORAGE

Omeprazole Oral Suspension should be protected from light and stored at a temperature of 2° to 8°.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Omeprazole.