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Lansoprazole Gastro-resistant Tablets

General Notices

Gastro-resistant Lansoprazole Tablets

Action and use

Proton pump inhibitor; treatment of peptic ulcer disease.

DEFINITION

Lansoprazole Gastro-resistant Tablets contain Lansoprazole. They are covered with a gastro-resistant coating or prepared from granules or particles covered with a gastro-resistant coating.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of lansoprazole, $C_{16}H_{14}F_3N_3O_2S$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A Shake a quantity of the powdered tablets containing 30 mg of Lansoprazole with 50 mL of *methanol*, filter and dilute 1 volume to 50 volumes. The *light absorption*, Appendix II B, in the range 220 nm to 350 nm exhibits a maximum at 285 nm.
B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

TESTS

Dissolution

Comply with the *dissolution test for tablets and capsules*, Appendix XII B1.

Mix 11 volumes of 0.25M *trisodium orthophosphate* and 22 volumes of 0.5M *anhydrous disodium hydrogen orthophosphate*, dilute to 100 volumes with *water* and adjust the pH, if necessary, to 11.0 with *orthophosphoric acid* or 10M *sodium hydroxide*, as appropriate (solution A).

Mix 1 volume of 10M *sodium hydroxide* with 99 volumes of *0.05M phosphate buffer solution pH 4.5* (solution B).

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 150 revolutions per minute.
(b) Use as the media the solutions described sequentially below.

First stage (pH 4.5)

Use as the medium 700 mL of *0.05*M *phosphate buffer solution pH 4.5*. After 45 minutes, withdraw 5 mL of the medium, filter, dilute to 25 mL with solution A and retain the samples for analysis as described below. Proceed immediately to the final stage.

Final stage (pH 6.8)

Within 5 minutes, add 200 mL of solution B at 37° to the vessel. Maintain the rotation speed at 150 revolutions per minute and continue to operate the apparatus for 45 minutes. Withdraw 5 mL of the medium, filter, dilute to 25 mL with solution A and retain the samples for analysis as described below.

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

(1) The sample solutions taken above.
(2) Dissolve a sufficient quantity of *lansoprazole BPCRS* in solution A and dilute with sufficient *water* to produce a final solution of the same concentration as that expected for solution (1).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the total content of $C_{16}H_{14}F_3N_3O_2S$, in the medium using the declared content of $C_{16}H_{14}F_3N_3O_2S$ in *lansoprazole BPCRS*.

LIMITS

The amount of lansoprazole released after the first stage is not more than 10% of the stated amount. The amount of lansoprazole released after the final stage is not less than 75% (Q) of the stated amount.

Related substances

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

Mix 1 volume of *triethylamine* with 60 volumes of *water*, adjust the pH to 10.5 using *orthophosphoric acid*, add 40 volumes of *acetonitrile* and mix (solvent A).

(1) Shake a quantity of the powdered tablets containing 50 mg of Lansoprazole with 50 mL of solvent A and filter.
(2) Dilute 1 volume of solution (1) to 100 volumes with solvent A and dilute a further 1 volume to 5 volumes with solvent A.
(3) Dilute 1 volume of solution (2) to 4 volumes with solvent A.
(4) 0.1% w/v of *lansoprazole impurity standard BPCRS* in solvent A.
(5) 0.0003% w/v of *2-mercaptobenzimidazole* (impurity E) in solvent A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *amidohexadecylsilyl silica gel for chromatography* (5 µm) (Supelcosil LC-ABZ is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 285 nm.
(f) Inject 10 µL of each solution.
(g) Identify any peaks in the chromatogram obtained with solution (1) corresponding to lansoprazole impurities A and B using solution (3).

MOBILE PHASE

1 volume of *triethylamine*, 60 volumes of *water*, adjusted to pH 6.2 using *orthophosphoric acid* and mix the solution with 40 volumes of *acetonitrile*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the *resolution* between the peaks due to lansoprazole and impurity B is at least 3.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity A is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%);

the area of any peak corresponding to impurity B is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (0.4%);

the area of any peak corresponding to impurity E is not greater than the area of the principal peak in the chromatogram obtained with solution (5) (0.3%);

the area of any other *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas of all the *secondary peaks* is not more than 2.0%.

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (3) (0.05%).

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in solvent A, protected from light.

Mix 1 volume of *triethylamine* with 60 volumes of *water*, adjust the pH to 10.5 using *orthophosphoric acid*, add 40 volumes of *acetonitrile* and mix (solvent A).

(1) To a quantity of the powdered tablets containing 50 mg of Lansoprazole add 50 mL of solvent A, shake for 30 minutes and filter. Dilute 1 volume to 5 volumes with solvent A.
(2) 0.02% w/v of *lansoprazole BPCRS*.
(3) 0.01% w/v of *lansoprazole impurity standard BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

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

DETERMINATION OF CONTENT

Calculate the content of lansoprazole, $C_{16}H_{14}F_3N_3O_2S$, in the tablets using the declared content of $C_{16}H_{14}F_3N_3O_2S$ in *lansoprazole BPCRS*.