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Lansoprazole Oral Suspension

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

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

Expert Advisory Group ULM:	Unlicensed Medicines
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Deadline for Comment	31st December 2024
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Notes:	New monograph

Action and use

Proton pump inhibitor; treatment of peptic ulcer disease.

DEFINITION

Lansoprazole Oral Suspension is a suspension of Lansoprazole 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 lansoprazole, $C_{16}H_{14}F_3N_3O_2S$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Dilute a quantity of the oral suspension with *methanol* to contain 0.001% w/v of Lansoprazole and filter. 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 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).

TESTS

Dissolution

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

Related substances

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

Solution A: 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.

(1) Disperse a quantity of the oral suspension in sufficient solution A to produce a solution containing 0.1% w/v of Lansoprazole and filter.
(2) Dilute 1 volume of solution (1) to 100 volumes and further dilute 1 volume to 5 volumes.
(3) Dilute 1 volume of solution (2) to 4 volumes.
(4) 0.1% w/v of *lansoprazole impurity standard BPCRS*.
(5) 0.0003% w/v of *2-mercaptobenzimidazole* (impurity E).

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.

MOBILE PHASE

Mix 1 volume of *triethylamine* and 60 volumes of *water* and adjust to pH 6.2 using *orthophosphoric acid*; mix this 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

Identify any peaks in the chromatogram obtained with solution (1) corresponding to lansoprazole impurities A and B using solution (3).

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 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

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

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

Solution A: 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.

(1) Disperse a weighed quantity of the oral suspension in sufficient solution A to produce a solution containing 0.02% w/v of Lansoprazole and filter.
(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 Assay 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

Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_{16}H_{14}F_3N_3O_2S$, weight in volume, using the declared content of $C_{16}H_{14}F_3N_3O_2S$ in *lansoprazole BPCRS*.

STORAGE

Lansoprazole 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 impurities A, B and E listed under Lansoprazole.