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Rifaximin Tablets

General Notices

Action and use

Antibacterial; treatment of infective diarrhoea.

DEFINITION

Rifaximin Tablets contain Rifaximin.

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

Content of rifaximin, $C_{43}H_{51}N_3O_{11}$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 210 to 400 nm:

the UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

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

Related substances

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

(1) Disperse a quantity of the powdered tablets containing 0.25 g of Rifaximin with the mobile phase. Dilute to 50 mL and filter through a 0.45-µm filter (Whatman GF-C filter is suitable).
(2) Dilute 1 volume of solution (1) to 200 volumes.
(3) 0.125% w/v of *rifaximin for system suitability EPCRS*.
(4) Dilute 1 volume of solution (2) to 5 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm x 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Alltima C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.4 mL per minute.
(d) Use a column temperature of 40°.

(e) Use a detection wavelength of 276 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for 3 times the retention time of rifaximin.

MOBILE PHASE

37 volumes of a 0.316% w/v solution of *ammonium formate*, adjusted to pH 7.2 using *dilute ammonia R1* and 63 volumes of a mixture of equal volumes of *acetonitrile* and *methanol*.

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to rifaximin (retention time about 12 minutes) are: impurities D and H, about 0.7.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peak due to impurities D and H and the peak due to rifaximin is at least 3.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurities D and H 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 twice the area of the principal peak in the chromatogram obtained with solution (4) (0.2%);

the sum of the areas of any *secondary peaks* is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (1.5%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

Water

The tablets contain not more than 8.0% w/w of *water*, Appendix IX C, Method I. Use 0.1 g.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in the mobile phase.

(1) Shake a portion of the powdered tablets containing 0.5 g of Rifaximin with mobile phase and dilute to 100 mL. Filter, and dilute the filtrate to produce a solution containing 0.004% w/v of Rifaximin.
(2) 0.004% w/v of *rifaximin EPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions under the Related substances may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{43}H_{51}N_3O_{11}$, in the tablets from the chromatograms obtained and using the declared content of $C_{43}H_{51}N_3O_{11}$ in *rifaximin EPCRS*.

IMPURITIES

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