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Aspirin Gastro-resistant Tablets

Gastro-resistant Aspirin Tablets

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

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Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. **Related substances** Method and limits revised

Action and use

Salicylate; non-selective cyclo-oxygenase inhibitor; antipyretic; analgesic; anti-inflammatory.

DEFINITION

Aspirin Gastro-resistant Tablets contain Aspirin. They are made gastro-resistant by enteric-coating or by other means.

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

Content of aspirin, $C_9H_8O_4$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 0.5 g of Aspirin with 20 mL of *absolute ethanol*, filter (Whatman GF/C is suitable), evaporate the filtrate and dry the residue at 60° for 1 hour. The *infrared absorption spectrum* of the residue, is concordant with the *reference spectrum* of aspirin *(RS 483)*.

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

First stage

(a) Use Apparatus 1, rotating the basket at 100 revolutions per minute.

(b) Use 1000 mL of 0.1M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 2 hours, withdraw a sample of the medium, filter and measure the *absorbance* of the filtrate, Appendix II B, at 276 nm using 0.1M *hydrochloric acid* in the reference cell.

(2) Measure the *absorbance* of a suitable solution of *aspirin BPCRS* in 0.1M *hydrochloric acid*.

DETERMINATION OF CONTENT

Calculate the total content of aspirin, $C_9H_8O_4$, in the medium using the declared content of $C_9H_8O_4$ in *aspirin BPCRS*. The amount of aspirin released is not more than 5% of the stated amount.

Final stage

(a) Use Apparatus 1, rotating the basket at 100 revolutions per minute.

(b) Replace the 0.1M *hydrochloric acid* in the vessel with 900 mL of *mixed phosphate buffer pH 6.8*, previously held at 36.5° to 37.5°.

PROCEDURE

(1) After 45 minutes, withdraw a sample of the medium and filter. Immediately measure the *absorbance* of the filtrate, Appendix II B, diluted with the dissolution medium, if necessary, at 265 nm using dissolution medium in the reference cell.

(2) Measure the *absorbance* of a suitable solution of *aspirin BPCRS* in the dissolution medium.

DETERMINATION OF CONTENT

Calculate the total content of aspirin, $C_9H_8O_4$, in the medium using the declared content of $C_9H_8O_4$ in *aspirin BPCRS*.

Related substances

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

(1) Mix with the aid of ultrasound for 15 minutes a quantity of the powdered tablets containing 0.10 g of Aspirin with 40 mL of *acetonitrile*, allow to cool, dilute to 100 mL with *water* and filter through a 0.45-µm PTFE filter.

(2) Dilute 1 volume of solution (1) to 50 volumes and further dilute 1 volume of the resulting solution to 10 volumes with the mobile phase.

(3) 0.001% w/v of *salicylic acid* (impurity C) in the mobile phase.

(4) 0.1% w/v of *aspirin impurity standard BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Kromasil C18 is suitable).

(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 1.0 mL per minute.

(d) Use an ambient column temperature.

(e) Use a detection wavelength of 237 nm.

(f) Inject 20 µL of each solution.

(g) Allow the chromatography to proceed for 1.2 times the retention time of impurity F.

MOBILE PHASE

2 volumes of *orthophosphoric acid*, 400 volumes of *acetonitrile* and 600 volumes of *water*.

When the chromatograms are recorded under the prescribed conditions, the retention times relative to aspirin (retention time about 5 minutes) are: impurity A, about 0.6; impurity B, about 0.7, impurity C, about 1.4 and impurity F, about 8.0.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4) the *resolution* between the peaks due to aspirin and impurity C is at least 6.

LIMITS

Use the chromatogram supplied with *aspirin impurity standard BPCRS* and the chromatogram obtained with solution (4) to identify the peaks due to due to impurities A, B, C and F. Multiply the area of any peak corresponding to impurity B by a correction factor of 0.7.

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity C is not greater than three times the area of the principal peak in the chromatogram obtained with solution (3) (3%);

the area of any peak corresponding to impurities A, B, D, E or F is not greater than 0.15 times the area of the principal peak in the chromatogram obtained with solution (3) (0.15% of each)

the area of any other *secondary peak* is not greater than half the area of the principal peak in the chromatogram obtained with solution (2) (0.10%);

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

Disregard any peak with an area less than 0.25 times the area of the principal peak in the chromatogram obtained with solution (2) (0.05%).

ASSAY

Weigh and powder 20 tablets. Carry out the method for *Liquid Chromatography*, Appendix III D, using the following solutions.

(1) Mix with the aid of ultrasound for 15 minutes a quantity of the powdered tablets containing 60 mg of Aspirin with 40 mL of *acetonitrile*, allow to cool, dilute to 100 mL with *water* and filter through a 0.45-µm PTFE filter.

(2) 0.06% w/v of *aspirin BPCRS* in the mobile phase.

(3) 0.1% w/v of *aspirin impurity standard BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure 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 aspirin and impurity C is at least 6.0.

DETERMINATION OF CONTENT

Calculate the content of $C_9H_8O_4$ in the tablets from the chromatograms obtained using the declared content of $C_9H_8O_4$ in *aspirin BPCRS*.

STORAGE

Aspirin Gastro-resistant Tablets should be protected from moisture.

LABELLING

The label states that the tablets contain Aspirin, unless this word appears in the name of the tablets (this requirement does not apply in countries where exclusive proprietary rights in the name Aspirin are claimed).

IMPURITIES

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