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Aspirin Dispersible Tablets

Dispersible 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 Dispersible Tablets contain Aspirin in a suitable dispersible basis.

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

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 with the mobile phase 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) For solution (1), 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 retentions 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 6.0.

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 prepared immediately before use.

(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*.

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).

When Aspirin Dispersible Tablets are prescribed or demanded, no strength being stated, tablets containing 300 mg shall be dispensed or supplied.

When Aspirin Soluble tablets are prescribed, Aspirin Dispersible Tablets shall be dispensed.

IMPURITIES

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