Favipiravir Tablets

Favipiravir Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of favipiravir C₅H₄FN₃O₂.

Usual strength. 200 mg.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

Dissolution (2.5.2).

Apparatus No. 1,

Medium: 900 ml of buffer solution, prepared by dissolving 3 g of sodium acetate trihydrate in 900 ml of water, adjusted to pH 4.5 with glacial acetic acid and dilute to 1000 ml with water.

Speed and time. 75 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtered solution, dilute suitably with the dissolution medium if necessary, at the maximum at about 322 nm (2.4.7). Calculate the content of C₅H₄FN₃O₂ in the medium from the absorbance obtained from a solution prepared by dissolving 44 mg of favipiravir RS in 10 ml of acetonitrile and dilute to 200.0 ml with the dissolution medium, and dilute the solution with the dissolution medium to obtain the concentration similar to the expected concentration in the test solution.

D. Not less than 70 per cent of the stated amount of C₅H₄FN₃O₂.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 50 volumes of water and 50 volumes of acetonitrile.

Test solution. Disperse a quantity of powdered tablets containing 250 mg of Favipiravir in 200 ml of the solvent mixture, with the aid of ultrasound with intermittent shaking for 30 minutes, cool and dilute to 250.0 ml with the same solvent, filter.

Reference solution (a). A 0.025 per cent w/v solution of favipiravir RS in the solvent mixture.

Reference solution (b). Dilute 2.0 ml of reference solution (a) to 100.0 ml with the solvent mixture.

Chromatographic system

– a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 μm) ( Such as Intersil ODS 3V),
– mobile phase:  A. a 0.1 per cent v/v solution of orthophosphoric acid,
  B. acetonitrile,
– a gradient programme using the conditions given below,
– flow rate: 1 ml per minute,
– spectrophotometer set at 225 nm,
– injection volume: 10 μl.

<table>
<thead>
<tr>
<th>Time (in min.)</th>
<th>Mobile phase A (per cent v/v)</th>
<th>Mobile phase B (per cent v/v)</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>90</td>
<td>10</td>
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<tr>
<td>30</td>
<td>35</td>
<td>65</td>
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<td>40</td>
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<tr>
<td>42</td>
<td>90</td>
<td>10</td>
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<tr>
<td>50</td>
<td>90</td>
<td>10</td>
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</tbody>
</table>
Inject reference solution (b). The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 5.0 per cent.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent) and the sum of areas of all the secondary peaks is not more than 4 times the area of the principal peak in the chromatogram obtained with reference solution (b) (2.0 per cent).

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. 50 volumes of water and 50 volumes of acetonitrile.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powder containing 250 mg of Favipiravir in 200 ml of the solvent mixture, with the aid of ultrasound with intermittent shaking for 30 minutes, cool and dilute to 250.0 ml with the same solvent, filter. Dilute 5.0 ml of the solution to 100.0 ml with the solvent mixture.

Reference solution. A 0.005 per cent w/v solution of favipiravir RS in the solvent mixture.

Chromatographic system
– a stainless steel column 25 cm x 4.6 mm, packed with octadecysilane bonded to porous silica (5 μm) (Such as Intersil ODS 3V),
– mobile phase: a mixture of 77 volumes of 0.1 per cent v/v solution of orthophosphoric acid and 23 volumes of acetonitrile,
– flow rate: 1 ml per minute,
– spectrophotometer set at 225 nm,
– injection volume: 20 μl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of the C₅H₅FN₃O₂.

Storage. Store protected from moisture, at a temperature not exceeding 30°C.