DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Favipiravir Tablets

Analytical Profile No.: Favi 077/078/AP 083

Favipiravir Tablets contains not less than 90% and not more than 110% of the stated amount of Favipiravir.

Usual Strength: 200 mg

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Favipiravir.

2. Dissolution:

2.1 Dissolution Parameters: *Deteremine by UV-Vis spectrophotometer*

Apparatus: Paddle

Medium: 900ml of Acetate buffer, pH 4.5 prepared by dissolving 21 gm of Sodium acetate trihydrate and 9 ml glacial acetic acid in 1 litre water, making up the volume to 7 litres with water and adjusting pH to 4.5 with glacial acetic acid.

Speed and Time: 75 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 1 ml of the filtrate to 20 ml with dissolution medium.

2.3 Reference Solution: Weigh accurately about 22 mg of Favipiravir WS in 100 ml volumetric flask. Add 5 ml of Acetonitrile to dissolve and dilute to 100 ml with dissolution medium. Further dilute 1 ml of the solution into 20 ml with dissolution medium.

2.4 Procedure: Measure the absorbance of the reference and test solutions at the wavelength of maxima at 322 nm using dissolution medium as blank.

Calculate the content of Favipiravir.

2.5 Limit:

D. Not less than 70 percent of the stated amount of Favipiravir.

3. Assay: *Determine by liquid chromatography*

3.1 Solvent Mixture: 50 volumes of Acetonitrile and 50 volumes of Water

3.2 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 100 mg of Favipiravir in 100 ml volumetric flask, add about 70 ml of solvent mixture, sonicate for 30 minutes with intermittent shaking and make volume to 100 ml with same solvent. Further dilute 5 ml of this solution to 100 ml with same solvent.

3.3 Reference Solution: Weigh accurately about 20 mg of Favipiravir WS in 20 ml volumetric flask. Add about 14ml of solvent mixture, sonicate to dissolve and make up the volume to 20 ml with same solvent. Further dilute 5 ml of this solution to 100 ml with same solvent.

3.4 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µm; Proprietary name: Inertsil ODS-3, 5 µm
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 225 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Mobile Phase:** A mixture of 77 volumes of buffer and 23 volumes of Acetonitrile
- **Buffer:** 0.1% orthophosphoric acid in water

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

Calculate the content of Favipiravir in the tablets.

4. Other tests: As per pharmacopoeial requirements.