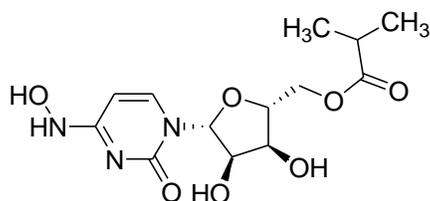


Molnupiravir



$C_{13}H_{19}N_3O_7$

Mol. Wt. 329.3

Molnupiravir is ((2R,3S,4R,5R)-3,4-dihydroxy-5-(4-(hydroxyamino)-2-oxopyrimidin-1(2H)-yl)tetrahydrofuran-2-yl) methyl isobutyrate.

Molnupiravir contains not less than 97.5 per cent and not more than 102.0 per cent of $C_{13}H_{19}N_3O_7$, calculated on the anhydrous and solvent free basis.

Category. Antiviral.

Description. A white to off-white powder.

Identification

- Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *molnupiravir IPRS* or with the reference spectrum of molnupiravir.
- 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

Specific optical rotation (2.4.22). -12.0° to -6.0° , determined in a 1.0 per cent w/v solution in *methanol*.

Related substances. Determine by liquid chromatography (2.4.14).

Buffer solution. Dissolve 2.3 g of *ammonium dihydrogen phosphate* in 1000 ml of *water*.

Solvent mixture. 95 volumes of the buffer solution and 5 volumes of *acetonitrile*.

Test solution. Dissolve 50 mg of the substance under examination in the solvent mixture, with the aid of ultrasound and dilute to 50.0 ml with the solvent mixture.

Reference solution. A 0.001 per cent w/v solution of *molnupiravir IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (3.0 μ m) (Such as Atlantis T3),
- column temperature: 40 $^\circ$,
- mobile phase: A. a mixture of 1 volume of *methanol* and 100 volumes of buffer solution,
B. *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 260 nm,
- injection volume: 5 μ l.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
5	100	0
45	20	80
52	20	80

Inject the reference solution. The test is not valid unless the column efficiency is not less than 5000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 1.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{13}H_{19}N_3O_7$.

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

2.4.26. Solubility Molnupiravir. Soluble in *methanol*.