

**Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section**

Analytical profile of Vonoprazan Tablets

Analytical Profile No.: Vono 082/83/AP 179

Vonoprazan Tablets contain not less than 90.0% and not more than 110.0% of the stated amount of Vonoprazan.

Usual Strength: 10 mg, 20 mg

1. 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.

2. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml of Acetate Buffer pH 4.5 (Dissolve 2.99 gm sodium acetate trihydrate and 14 ml of 2N glacial acetic acid in 1000 ml purified water. Adjust to 4.5 with glacial acid or 2 N sodium hydroxide solution.)

Speed and Time: 50 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Diluent: 30% Acetonitrile

2.3 Test Solution: Use the filtrate.

2.4 Reference Solution: Weigh 53.5 mg of Vonoprazan Fumerate RS accurately and transfer in 100 ml of a completely dried volumetric flask. Add about 50 ml of diluent and sonicate for about 10 minutes to dissolve and make up the volume to 100 ml with the same diluent. Dilute 2 ml of the resulting solution to 100 ml with the dissolution medium.

2.5 Procedure: Use the chromatographic system as described in the Assay using 10 μ l as injection volume. Inject the reference solution and the test solution. Calculate the percent release of Vonoprazan.

2.6 Limit: NLT 80 % (Q) of the stated amount.

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3. Uniformity of Content:

Determine by liquid chromatography, as described in the Assay, using the following test solution.

Test Solution: Place one tablet in each of 10 separate 50 ml volumetric flasks. Dissolve in about 25 ml diluent with the aid of sonication for 15 minutes and make up the volume to 50 ml with the same diluent. Dilute 2 ml of the resulting solution to 25 with diluent and mix.

4. Assay: *Determine by liquid chromatography*

4.1 Diluent: 30% acetonitrile

4.2 Test solution: Weigh the content of 20 tablets and calculate the average weight. Transfer an accurately weighed powder equivalent to 20 mg of Vonoprazan into 50 ml volumetric flask, add 25 ml of the diluent and dissolve by sonicating for 15 minutes, and cool the sample solution to room temperature. Make up the volume with the same diluent. Dilute 2 ml of the resulting solution to the 25 ml with diluent.

4.3 Reference solution: Weigh 53.5 mg of Vonoprazan Fumerate RS accurately and transfer in 100 ml of a completely dried volumetric flask. Add about 70 ml of diluent and sonicate for about 10 minutes to dissolve and make up the volume to 100 ml with the same diluent. Dilute 2 ml of the resulting solution to 25 ml with the same diluent.

4.4 Chromatographic system:

Column: C18 (4.6mmX 150mm, 3 μ m)

Flow rate: 1.0 ml/min

Wavelength: 230 nm

Injection volume: 10 μ l

Column Temperature: 40°C

Mobile Phase: Acetonitrile: Buffer: 30:70 (V/V)

Buffer: Weigh 10.743 g of disodium Hydrogen Phosphate Dodecahydrate in 1000 ml of HPLC grade water, and mix. Adjust pH 6.5 (+/- 0.05) with orthophosphoric acid.

4.5 Procedure: Inject the reference solution five times and sample solutions. 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

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the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses.

Calculate the content of Vonoprazan.

5. Other tests: As per Pharmacopoeial requirements.

Subject to approval from DAC