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**Original Research Article**

# Method Development and Validation of Vonoprazan Fumarate Tablets by Uv-Visible Spectroscopy

Nithesh. R[1], Prakash. N[1], Nithish dhayalan[1], K. S, Kapilan[1], S, Sekar. V[1], Krishnan. R[1]*, Mohanapriya. N[1]

[1]Department of Pharmaceutical Analysis, J. K. K. Nattraja College of Pharmacy, Kumarapalayam-638613, Tamil Nadu, India, Affiliated to The Dr. M.G.R. Medical University, Chennai, Tamil Nadu, India

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***Corresponding author:** Krishnan. R
Department of Pharmaceutical Analysis, J. K. K. Nattraja College of Pharmacy, Kumarapalayam-638613, Tamil Nadu, India, Affiliated to the Dr. M.G.R. Medical University, Chennai, Tamil Nadu, India

## Abstract

A simple, accurate, and cost-effective UV spectrophotometric method was developed and validated for the estimation of Vonoprazan fumarate in tablet dosage form. The solvent system utilized was 0.1N hydrochloric acid, and the drug exhibited a maximum absorbance (λmax) at 281 nm. The method obeyed Beer–Lambert's law within the concentration range of 10–50 µg/ml with a correlation coefficient ($r^2$) of 0.9997, indicating excellent linearity. The assay value was found to be 100.3% w/v, within the acceptable range of 90–110%. Precision and accuracy studies yielded results of 99.86% and 99.88%, respectively. The LOD and LOQ were calculated to be 1.557 µg/ml and 4.719 µg/ml. Validation was carried out as per ICH guidelines for parameters such as linearity, accuracy, precision, robustness, and ruggedness, with %RSD values less than 2%, confirming the reliability of the method. The developed method proved to be simple, rapid, and precise, making it suitable for routine quality control analysis of Vonoprazan fumarate in pharmaceutical formulations.

**Keywords:** Vonoprazan fumarate, UV spectrophotometry, Method validation, ICH guidelines, Linearity, Precision, Accuracy, Quality control.



## 1. INTRODUCTION

Spectroscopy is a general term for the science that deals with the interaction of various types of radiation with matter. It is defined as Measurement and Interpretation of electromagnetic Radiation Absorbed or Emitted when the molecules or ions or atoms of sample moves from one energy state to another energy state. In another words, Spec- troscopy measures the changes in Rotational, Vibration and Electronic changes. Spec-trometric methods are large group of analytical methods that are based on atomic and molecular Spectroscopy.

### Ultraviolet spectroscopy

Ultraviolet spectroscopy is a type of molecular spectroscopy where changes in energy takes place at molecular level. It is based on the Principle of Absorption where the wavelength region is between 200-400nm.The valence electrons absorbs the energy and the molecule undergoes transition from ground state to excited state.

### Electronic Transitions

Ultraviolet light absorption relates to the excitation of electrons in atoms and molecules from lower to higher energy levels. Only light that is precisely enough to produce a transition from one level to another will work since matter's energy levels are quantized will be taken in. In each case the electron is excited from lower energy (ground state) to higher energy (excited state). The electronic transition is between both bonding orbitals and antibonding orbitals. This results in higher frequency and there- fore shorter wavelength being absorbed. All molecules will undergo electronic excitation which is followed by absorption of light.

### Qualitative Analysis

**a) Detection of impurities**

To limit the presence of impurities we can use UV Spectrophotometric measurements. Additional peaks can be due to impurities in the sample.

**b) Structural analysis of organic compounds**

Some of the aspects of Structural analysis are already discussed under electronic transition

- Effect of conjugation
- Effect of cross conjugation

**c) Structure elucidation of organic compounds**

It helps in structure elucidation of organic compounds. The presence or absence of sat- uration the presence of heteroatoms can be determined.

**Quantitative analysis**

- Using spectrophotometer to determine concentration of Metal ions.
- Physio-Chemical Parameters:
- Acid dissociation constant.
- Complex formation constant.
- Partition distribution coefficient.
- Dissolution test.

**VALIDATION**

It is a process of establishing documented evidence which provide a high degree of assurance that a specific process will consistently produce a product meeting it's predetermined specification and quality.

**The types of validation are**

- Analytical method validation
- The parameters to be considered during the Analytical procedure are:
- Specificity
- Assay
- Accuracy
- Precision
- Detection limit
- Quantitation limit
- Linearity

**Accuracy**

The accuracy of an analytical procedure expresses the closeness of agreement be- tween the value which is accepted either as a conventional true value or an accepted reference value and the value found. This is sometimes termed trueness.

**Precision**

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

**Quantitation Limit**

The quantitation limit of an individual analytical procedure is the lowest amount of analyst in a sample which can be quantitatively determined with suitable precision and accu- racy.

**Detection limit**

Detection limit of an individual analytical procedure is the lowest amount of an analyst in a sample which can be detected but not necessarily quantified as an exact value.

**Linearity**

The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyst in the sample.

## 2. AIM

A drug may define as a substance mean for a diagnosis, cure, prevention, treatment of the Disease in the human or animals for altering the structure or function. Analytical method development and validation can be understood as the of showing that analytical procedures are adequate for the purpose of assessing drugs. The aim and scope of developing and validating an analytical method is to ensure a suitable method which is more specific, accurate and pre- cise. It is to improve the parameters. The literature review indicates that few methods were developed and reported for vonoprazan fumarate, using solvents such as ethanol, Methanol, and acetonitrile. The objective of the present work is to develop a new method which was an easier way to analyst the vonoprazan fumarate tablets.

## 3. PLAN OF WORK

- Determination of solubility of vonoprazan fumarate.
- Selection of λ max for vonoprazan fumarate.
- To develop a method which is simple, rapid, cost effective
- The developed method is validated by various parameters like

- Linearity
- Assay
- Precision
- Recovery study
- LOD (limit of detection) & LOQ (limit of quantification)

## 4. MATERIALS AND METHODS

**MATERIALS:** Drug Sample

- **Formulation:** Vonoprazan Fumarate tablet-10mg (Voquezna-10)
- **Pure drug:** Voquezna

(The pure drug is purchased from Dhamtec Pharma and Consultants, Navy Mumbai.)

***Chemicals and Reagent:***

- Phenacetin, bupropion, tolbutamide, dextromethorphan, midazolam, Chlorzoxazone, and the diazepam (all purity> 98%)
- Distilled water

**Instruments:**

- Double beam UV/Visible Spectrophotometer (Lab India UV 3000) – UV Win Software.

## 5. METHOD DEVELOPMENT AND VALIDATION

**METHOD DEVELOPMENT:**

**Selection of solvent:**

The solvent is selected based on solubility process. So, the solubility has been tested for the vonoprazan fumarate to choose the solvent. We have tried to solubilize the vonoprazan fumarate in different type of solvent in. The vonoprazan fumarate was soluble in water, sparingly soluble in 0.1N HCL, and clearly soluble in dimethyl form amide, ethanol, methanol and DMSO. In HCL there is no method has been developed using vonoprazan fumarate. Finally Glacial acetic acid has been selected as solvent for performing the study.

**Determination of Absorption Maxima**

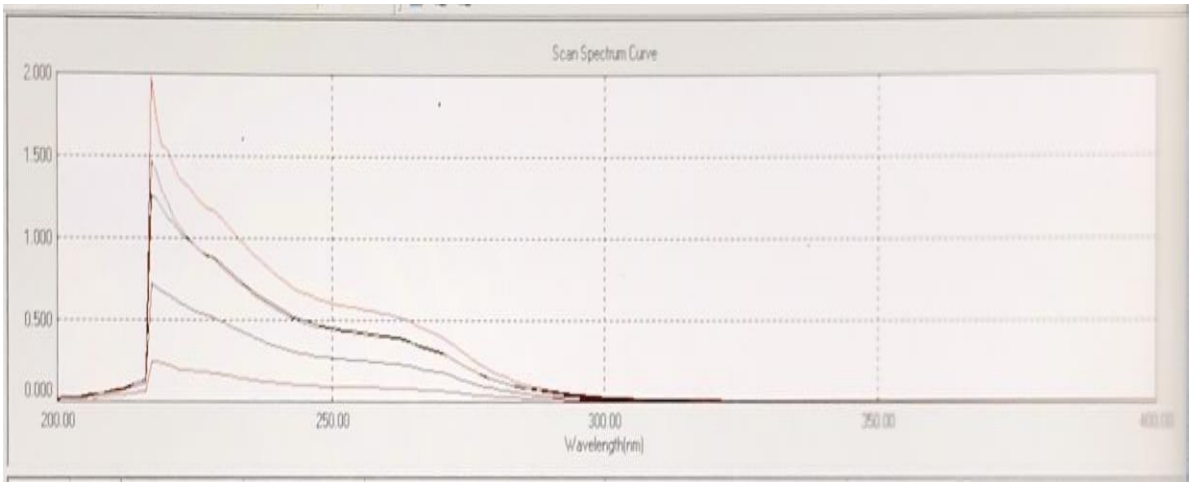


**Figure 1: Absorption maxima of Vonoprazan Fumarate**

Determination of maximum absorbance (λ max) of the drug, the Vonoprazan was dis- solved with 0.1N Hydrochloric acid to get the concentration 1mg/ml. From the above solution 0.1ml was taken and makeup with Ethanol (10µg/ml). The drug solution was scanned in UV-Visible spectrophotometer within the wavelength region of 200-400 nm against blank. The re- sulting spectrum was shown below figure: 6.1.1. The absorption curve showed characteristic absorbance maxima at 281nm for Vonoprazan fumarate.

**VALIDATION**

**Linearity**

100mg of Vonoprazan fumarate is weighed and transferred into a standard flask and dissolved with 100 ml of ethanol: 0.1N HCL: water. The content was shaken well to give a concentration of 1mg/ml. From the above solution, pipette out 0.1,0.2,0.3,0.4 and 0.5ml into an individual 10ml standard flask and makeup volume with 0.1N Hydrochloric acid. Each solution contains 10,20,30,40 and 50µg/ml. Absorbance of the solution is measured at 281nm against blank.

**Precision**

The precision of analytical method is the degree of agreement among individual test results when the method is applied repeatedly to multiple sampling of a homogenous sample. "Close- ness of agreement between measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions." The repeatability of the method was confirmed by the analysis of pure drug (Standard) and formulation (Sample) were repeated for 6 times with the same concentration. The amount of each drug present in the pure drug (Standard) and formulation (Sample) were calculated. The % RSD was calculated.

**Detection limit (LOD)**

The detection limit of an individual analytical procedure is the lowest amount of analytic a sample which can be detected but not necessarily quantitated as an exact value. The LOD was calculated by using the relation 3.3 respectively, where σ is the standard error of estimate and S is the slope.

**Quantification limit (LOQ)**

The Quantification limit of an individual analytical procedure is the lowest amount of analyst in a sample which can be quantitatively determined with suitable precision and accuracy

## 6. RESULT AND DISCUSSION

**Linearity**

The developed method was obeying the beers-lamberts law. The concentration and absorbance value of standard were tabulated in the table: 1 and the calibration curve was shown figure 2.

**Table: 1 The linearity data of Vonoprazan fumarate:**

| Concentrations (µg/ml) | Absorbance (217nm) |
|---|---|
| 0 | 0 |

| | |
|---|---|
| 10 | 0.326 |
| 20 | 0.627 |
| 30 | 0.924 |
| 40 | 1.219 |
| 50 | 1.477 |
| **r2value** | 0.9989 |
| **Slope value** | 0.0296 |
| **Intercept value** | **0.0221** |

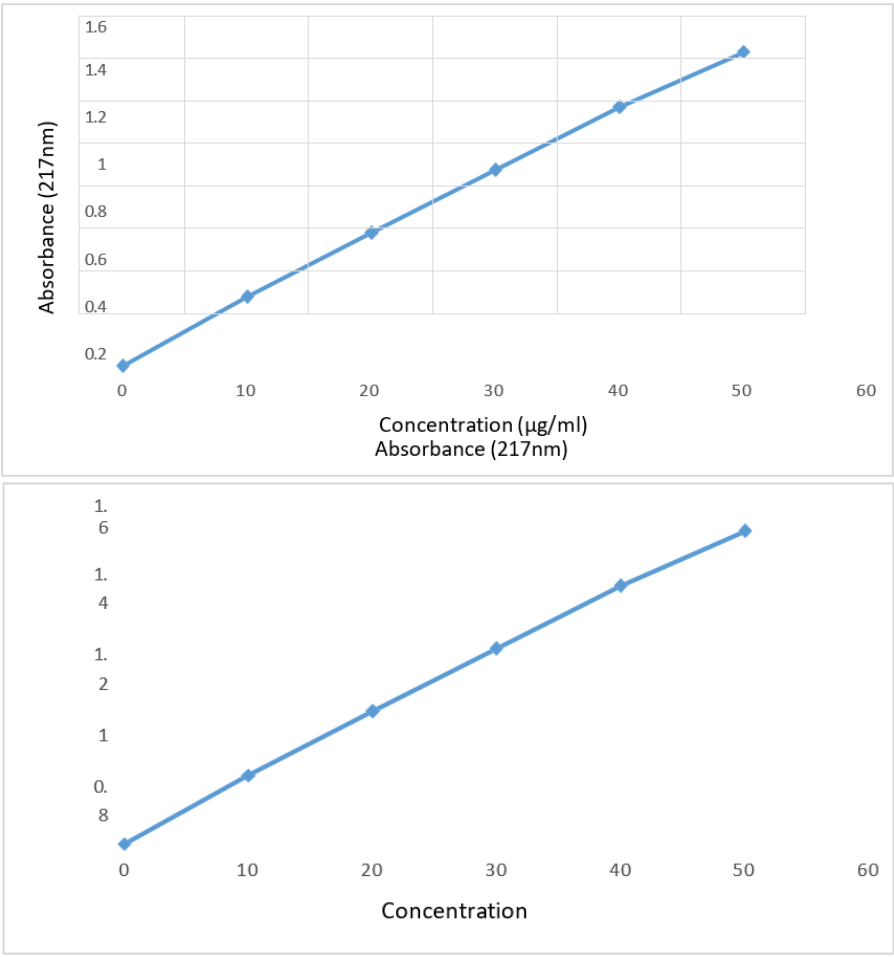


**Figure 2: Calibration curve of vonoprazan fumarate**

**Detection limit (LOD)**

The detection limit of an individual analytical procedure is the lowest amount of ana- lytic in sample which can be detected but not necessarily quantitated as an exact value (LOD) was found to be **0.247 µg/ml.**
The LOD is computed from the linearity plot:
LOD = **3.3(σ/s)**

= 3.3 x 19.08
254.09

LOD = 0.247

**Quantification limit (LOQ)**

The quantification limit of an individual analytical procedure is the lowest amount of analytic in a sample which can be quantitatively determined with suitable precision and accu- racy (LOQ) was found to be **0.750 µg/ml.**

The LOQ is computed from the linearity plot: LOQ = **10 (σ/s)**
= 10 x 19.08
254.09
LOQ = 0.750

## 7. SUMMARY AND CONCLUSION

A simple, rapid, and economical UV spectrophotometric method was developed and validated for the estimation of Vonoprazan fumarate. The drug showed maximum absorbance at 281 nm and obeyed Beer–Lambert's law in the concentration range of 10–50 µg/ml, with a correlation coefficient ($r^2$) of 0.9997. The assay value was found to be 100.3% w/v, within the acceptable limits (90–110%). Precision and accuracy

studies showed results of 99.86% w/v and 100.3% w/v, with recovery at 99.88%. The LOD and LOQ were determined as 1.557 µg/ml and 4.719 µg/ml, respectively. The method was validated as per ICH guidelines for linearity, precision, accuracy, robustness, and ruggedness. The %RSD values were within limits (< 2%), confirming reproducibility. Hence, the developed UV method is accurate, precise, and suitable for routine quality control analysis of Vonoprazan fumarate formulations.

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