# Formulation and Evaluation of Chewable Tablet of Vonoprazan Fumarate for Improve Patient Compliance

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*Abstract*—**Vonoprazan Fumarate is a novel potassium-competitive acid blocker (P-CAB) widely used for the treatment of gastroesophageal reflux disease, peptic ulcer, and Helicobacter pylori infection due to its rapid and long-lasting acid suppression activity.The present study aimed to formulate and evaluate chewable tablets of Vonoprazan Fumarate for improved patient compliance and ease of administration. The tablets were prepared by direct compression using suitable excipients, sweeteners, and superdisintegrants. Pre-compression and post-compression parameters were evaluated, including hardness, friability, weight variation, disintegration time, and drug release. The optimized formulation showed satisfactory tablet properties, rapid drug release, good stability, and acceptable palatability. The study concluded that Vonoprazan Fumarate chewable tablets are a promising dosage form for the treatment of acid-related disorders.**

*Index Terms*—**Vonoprazan Fumarate, Chewable tablet, Direct compression, Superdisintegrant ,Patient compliance.**

## I. Introduction

Chewable tablets are oral solid dosage forms intended to be chewed before swallowing. They are mainly developed for pediatric, geriatric, and dysphagic patients who experience difficulty in swallowing conventional tablets or capsules. These tablets improve patient compliance by providing better palatability, ease of administration, and convenience.

Chewable tablets disintegrate easily in the mouth, resulting in faster drug release and, in some cases, enhanced bioavailability. They are widely used for antacids, vitamins, analgesics, antihistamines, and cold remedies. Formulation of chewable tablets involves the use of excipients such as mannitol, sweeteners, and flavoring agents to mask unpleasant taste and provide a pleasant mouthfeel.

The tablets should possess adequat" hardness, low friability, good content uniformity, and acceptable disintegration properties. Common manufacturing methods include direct compression and wet granulation. According to the United States Pharmacopoeia (USP), chewable tablets may either be chewed for ease of administration or must be chewed before swallowing to ensure proper drug release and prevent choking.

Overall, chewable tablets are a patient-friendly dosage form that enhances therapeutic effectiveness, convenience, and patient acceptance**.**

**Definition:** According to FDA, "Chewable tablets are an immediate release (IR); oral dosage form intended to be chewed & then swallowed by the patient rather than swallowed whole."

## II. Materials and Methods

Vonoprazan Fumarate was supplied from Swapnroop Drug & Pharmaceuticals,Chhatrapati Sambhajinagar.Perlitol SD 200,calcium carbonate,PVP K30,sucralose,color received from Jinedra Scientific, Jalgaon.Crossprovidone,MCC PH102,Peppermint flavour was received from Medley Pharma Ltd.,Andheri.Aerosil from Vishal-Chem,Mumbai.Magnesium sterate from Loba Chemie, Mumbai.

**Compatibility Studies:**

**Fourier Transform Infrared Spectroscopy (FTIR):**

Fourier Transform Infrared Spectroscopy (FTIR) is an analytical technique used to identify chemical compounds and functional groups present in a sample. FTIR study was carried out using FTIR-1S Affinity instrument. The mixture of Vonoprazan Fumarate and excipients was analyzed to check possible drug‑excipient interactions. The results showed no significant interaction between the drug and excipients, indicating good compatibility.

**Design of Experiments:**

Differential Scanning Calorimetry (DSC) is used to study the thermal behavior of drugs and excipients. In this study, Vonoprazan Fumarate and excipients were analyzed in a 1:1 ratio to check drug–excipient compatibility.

The DSC thermogram of pure Vonoprazan Fumarate, pure Crospovidone, and the physical mixture of drug with excipients showed no significant change in characteristic peaks, indicating good compatibility and absence of major interaction between the drug and excipients.

**Table No.1:Independent Variables and Their Levels of Central Composition Design**

| Independent Variables | Unit | Levels | | | | |
|---|---|---|---|---|---|---|
| | | -�� | Low | Medium | High | +�� |
| Crossprovidone (X1) | % | 0.9465 | 2.5 | 6.25 | 10 | 11.55 |
| Perlitol SD 200 (X2) | % | 114.64 | 125 | 150 | 175 | 185.35 |

**Table No.2: Response Variables of Central Composite Design**

| Response Variables | Units |
|---|---|
| Disintegration Time (Y1) | Minutes |
| % Drug Release(Y2) | % |

## III. Formulation Table

**Table No.3: Composition of Batches by Central Composition design**

| Materials | Batches | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **V1** | **V2** | **V3** | **V4** | **V5** | **V6** | **V7** | **V8** | **V9** | **V10** |
| Vonoprazan fumarate | **13.36** | 13.36 | 13.36 | 13.36 | 13.36 | 13.36 | 13.36 | 13.36 | 13.36 | 13.36 |
| Perlitol SD 200 | **150** | 185.35 | 125 | 185.35 | 175 | 114.36 | 150 | 150 | 125 | 175 |
| Calcium carbonate | **8** | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| Crossprovidone | **6.25** | 6.25 | 2.5 | 6.25 | 10 | 6.25 | 11.5 | 6.25 | 10 | 2.5 |
| PVP K 30 | **8** | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| MCC PH 102 | **54.39** | 19.03 | 83.14 | 19.03 | 25.64 | 90.03 | 49.08 | 54.39 | 75.64 | 33.14 |
| Sucralose | **5** | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Peppermint flavour | **3** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Aerosil | **1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Magnesium sterate | **1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Colour | **q.s** | q.s | q.s | q.s | q.s | q.s | q.s | q.s | q.s | q.s |
| Total | **250** | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 |

## Method of Preparation of Vonoprazan Fumarate Chewable Tablet by Direct Compression:

Accurately weigh all ingredients according to the formula

Pass all ingredients through sieve no. 40, except magnesium stearate which is passed through sieve no. 60.

Mix Vonoprazan fumarate with Pearlitol SD 200 uniformly for 10 minutes.

Add calcium carbonate, crospovidone, PVP K-30, MCC PH 102, and sucralose and mix well for 5 minutes to obtain a uniform blend.

Add peppermint flavour and colour and mix for 2–3 minutes.

Add Aerosil and mix for 2 minutes.

Finally add magnesium stearate and blend gently for 1 minute.

Compress the prepared blend(250 mg) into tablets using an 8 mm round punch by direct compression method.

Collect the tablets and store them in a tightly closed container protected from moisture.

## IV. Evaluation Parameters of Chewable Tablet

**1. Pre-Compression Parameters:**

- **Bulk Density:**

Bulk density was determined by pouring a weighed quantity of tablet blend into a graduated cylinder and measuring the initial volume occupied by the powder. Bulk density is defined as the ratio of mass of powder to the bulk volume.

- **Tapped Density:**

An accurately weighed quantity of tablet blend was poured into a graduated cylinder and the initial volume was noted. The cylinder was then tapped 100 times on a hard surface until no further change in volume was observed.

- **Compressibility Index / Carr's Index:**

Compressibility index is used to evaluate the flow properties of powder blends. It indicates the ability of a powder to decrease in volume under pressure.

- **Hausner's Ratio:**

Hausner ratio is an indirect method used to determine the flow properties of powder blends and granules. It is calculated from the ratio of tapped density to bulk density.

- **Angle of Repose:**

Angle of Repose is defined as the maximum angle formed between the surface of a pile of powder and the horizontal plane. It is used to evaluate the flow property of powder blends.

**2. Post-Compression Parameters–**

- **Appearance:**

The prepared chewable tablets were pink coloured, circular in shape, smooth surfaced, elegant in appearance, and showed uniformity in size and thickness. Tablets were free from visible cracks, mottling, black spots, and capping.

- **Taste:**

The prepared Vonoprazan Fumarate chewable tablets showed a pleasant sweet taste with peppermint flavour.

- **Weight Variation:**

The weight variation test was performed by randomly selecting 20 tablets and weighing them individually using a digital balance. The average weight of tablets was calculated and compared with the individual tablet weights. The prepared Vonoprazan Fumarate chewable tablets were found to be within the official pharmacopeial limits.

- **Thickness:**

Tablet thickness is an important parameter related to tablet compression and packaging. It was measured using a Vernier caliper and expressed in millimeters (mm). Thickness of the tablets was maintained within ±5% variation of the standard value. Uniform thickness indicated proper die fill and compression of tablets.

- **Hardness:**

Hardness test was performed to determine the mechanical strength of the tablets.The hardness of tablets was measured using a Monsanto hardness tester. Randomly selected tablets were tested and the average hardness value was calculated and expressed in kg/cm². Uniform hardness indicated proper compression of tablet.

- **Friability:**

The test was carried out using a Roche friabilator. Pre-weighed tablets were rotated at specified speed and time, then reweighed after dusting.20 tablets were accurately weighed and placed in the friabilator. The apparatus was operated at 25 rpm for 4 minutes (100 revolutions).

- **Drug Content:**

Five tablets of each formulation were weighed and crushed in a mortar. Powder equivalent to 60 mg of Vonoprazan Fumarate Was weighed and dissolved in 100 ml of 0.1 N HCl. This was the stock solution from which 0.2 ml of solution was withdrawn and diluted to 10 ml with 0.1 N HCI. The absorbance of this solution was measured at wavelength 267.80 nm using double beam UV visible spectrophotometer.

- **In-Vitro Dissolution Study:**

The in-vitro dissolution study of Vonoprazan Fumarate chewable tablets (250 mg) was carried out using USP Type II dissolution apparatus. The study was performed in 900 mL of 0.1 N HCl at $37 \pm 0.5^0$C and 50 RPM. Samples were collected at 5, 10, 15, 30, 45, and 60 minutes and analyzed at 267 nm to determine the percentage drug release.

**Evaluation of Vonoprazan Fumarate Chewable Tablet Generated by CCD: Table**

**No.4:Pre-Compression Parameters of Batches Generated by CCD –**

| Pre Compression Parameters | Batches | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | VF1 | VF2 | VF3 | VF4 | VF5 | VF6 | VF7 | VF8 | VF9 | VF10 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Bulk Density (gm/ml)** | **0.44 ±0.01** | 0.49 ±0.4 | 0.46 ±0.00 | 0.48 ±0.01 | 0.43 ±0.01 | 0.48 ±0.03 | 0.51 ±0.06 | 0.44 ±0.01 | 0.49 ±0.4 | 0.47 ±0.01 |
| **Tapped Density (gm/ml)** | **0.51 ±0.03** | 0.55 ±0.08 | 0.54 ±0.00 | 0.55 ±0.02 | 0.50 ±0.00 | 0.57 ±0.07 | 0.64 ±0.07 | 0.51 ±0.03 | 0.55 ±0.08 | 0.55 ±0.01 |
| **Hausner's Ratio** | **��.�� ±0.01** | 1.14 ± 0.03 | 1.16 ± 0.01 | 1.14 ± 0.02 | 1.16 ± 0.00 | 1.18 ± 0.01 | 1.18 ± 0.01 | 1.14 ± 0.01 | 1.14 ± 0.03 | 1.14 ± 0.00 |
| **Carr's Index %** | **12.92 ±0.84** | 13.03 ±1.50 | 14.04 ±0.77 | 12.61 ±1.29 | 13.97 ±0.07 | 15.48 ±0.82 | 15.72 ±0.55 | 12.92 ±0.84 | 13.03 ±1.50 | 15.04 ±0.24 |
| **Angle of Repose** | **32.41 ±0.14** | 33.08 ±0.63 | 33.36 ±0.83 | 33.42 ±0.72 | 34.62 ±0.44 | 34.29 ±0.42 | 33.40 ±0.81 | 32.41 ±0.14 | 33.08 ±0.63 | 34.54 ±0.24 |

**Table No.5:Post-Compression Parameters of Batches Generated by CCD –**

| **Post-Compression Parameters** | **Batches** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **VF1** | **VF2** | **VF3** | **VF4** | **VF5** | **VF6** | **VF7** | **VF8** | **VF9** | **VF10** |
| **Weight Variation(mg)** | **249.33±0.67** | 248 ±1 | 248.66±1.6 | 249 ±1 | 248.66±1.34 | 249.33±0.6 | 248.33±1.67 | 249.33±0.67 | 248 ±2 | 248.66±1.34 |
| **Thickness(mm)** | **4.33± 0.01** | 4.32 ±0.01 | 4.34 ±0.00 | 4.31 ±0.01 | 4.31± 0.00 | 4.33 ±0.00 | 4.34± 0.01 | 4.33± 0.01 | 4.35 ±0.01 | 4.32± 0.00 |
| **Hardness(kg/cm 2)** | **��.�� ± 0.01** | 42 ± 0.01 | 4.5 ± 0.00 | 4.23 ±0.03 | 4.3 ± 0.00 | 4.66 ±0.04 | 4.6 ± 0.00 | 4.3 ± 0.01 | 4.7 ± 0.00 | 4.43 ± 0.03 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Friability (%)** | **0.41± 0.01** | 0.43 ±0.01 | 0.48 ±0.02 | 0.30 ±0.01 | 0.55± 0.01 | 0.55 ±0.03 | 0.46± 0.01 | 0.41± 0.01 | 0.47 ±0.02 | 0.44± 0.01 |
| **DT(min)** | **15** | 14 | 13 | 20 | 16 | 14 | 18 | 15 | 17 | 19 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Drug Content (%)** | **98.10** | 96.05 | 97 | 95 | 98.60 | 100.10 | 99.20 | 98.10 | 97.77 | 96 |

**Table No.6: % Drug Released of Batches Generated by CCD –**

| **Time (min)** | **%Drug Released** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Batches** | | | | | | | | | |
| | **VF1** | **VF2** | **VF3** | **VF4** | **VF5** | **VF6** | **VF7** | **VF8** | **VF9** | **VF10** |
| **0** | **0** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **5** | **71.90** | 65.2 | 35.44 | 45.62 | 52.71 | 46.63 | 49.16 | 71.90 | 43.59 | 54.74 |
| **10** | **85.06** | 70.89 | 53.16 | 56.77 | 60.32 | 54.74 | 57.27 | 85.06 | 54.23 | 61.84 |
| **15** | **87.09** | 81.01 | 61.77 | 66.40 | 67.41 | 64.88 | 67.41 | 87.09 | 68.43 | 70.45 |
| **30** | **89.12** | 83.04 | 76.96 | 80.08 | 74.51 | 78.56 | 79.58 | 89.12 | 78.56 | 80.59 |
| **45** | **94.18** | 90.13 | 90.13 | 90.73 | 89.72 | 92.76 | 93.77 | 94.18 | 88.19 | 90.73 |
| **60** | **97.22** | 95.19 | 96.21 | 94.18 | 97.83 | 99.24 | 98.33 | 97.22 | 96.81 | 95.19 |

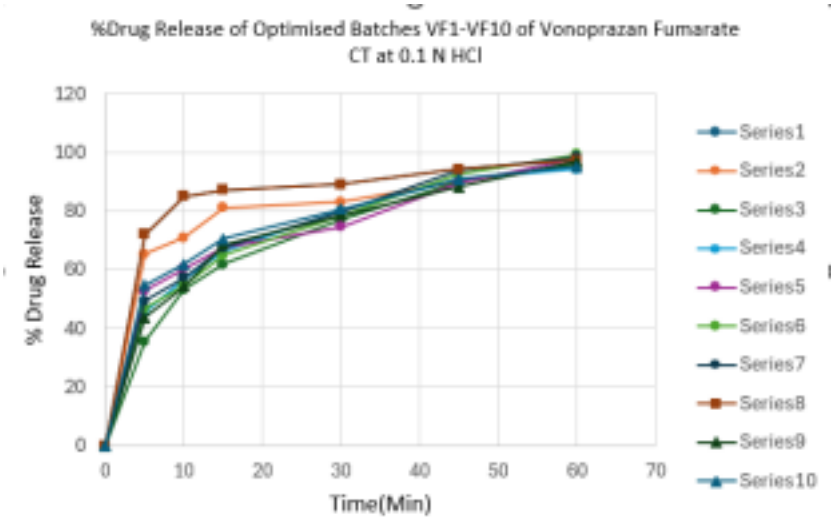


**Fig.No.1: In-Vitro Drug Release Study of Optimized Batches of Vonoprazan Fumarate CT Generated by CCD**

## Data Analysis

**1.%Drug Release:**

The final equation in coded form for percentage drug release was:

$$\%DR=96.74 -0. 8945X1 + 0.9601X2$$

The regression analysis showed that X1 ad a negative effect on % drug release, while X2 ad a positive effect. The optimized formulation showed a maximum drug release of 96.74%. ANOVA indicated that the model was significant as the obtained F-value was greater than the critical F-value ($p<0.05$).

## 2. Disintegration Time

The final equation for disintegration time was:

$$DT =15.00+2.66X-0.50X2$$

Here, X1 (Perlitol SD 200) showed a positive effect on disintegration time, whereas X2 (Crospovidone) showed a negative effect. ANOVA confirmed that the model was statistically significant ($p<0.05$).

**Table No.7: Result of Analysis of Variance for Batches by CCD of Vonoprazan Fumarate Chewable Tablet**

| | DF* | SS* | MS* | F* | P Value | |
|---|---|---|---|---|---|---|
| **Y1=%DR** | | | | | | |
| Model | 2 | 13.77 | 6.89 | 5.81 | 0.0326 | Significant |
| Residual | 7 | 8.30 | 1.19 | - | - | |
| Total | 9 | 22.07 | - | - | - | |
| **Y2=Disintegration** | | | | | | |
| Model | 2 | 58.78 | 29.39 | 28.51 | 0.0004 | Significant |
| Residual | 7 | 7.22 | 1.03 | - | - | |
| Total | 9 | 66.00 | - | - | - | |

***DF indicates degree of freedom; SS sum of square; MS mean sum of square and F is Fischer's ratio.**

## V. UV Estimationf Vonoprazan Fumarate

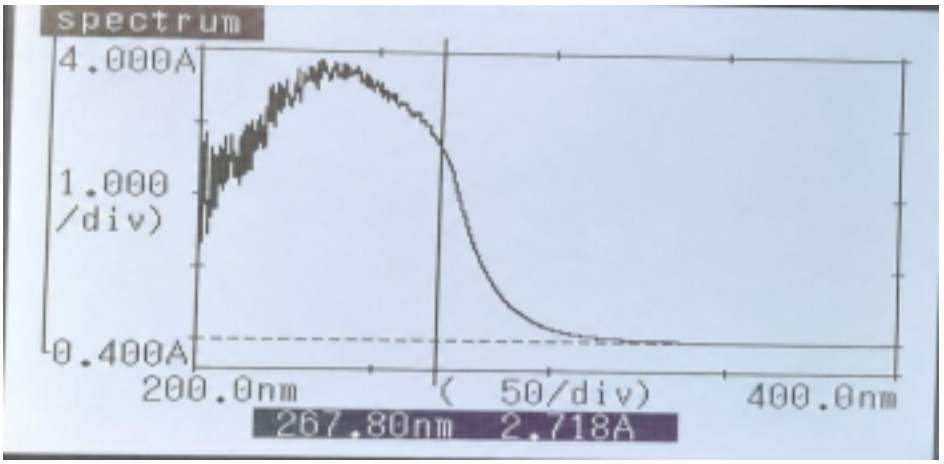


**Fig.No.2: Wavelength Maxima of Vonoprazan fumarate**

**Table No.8: Observation Table for Calibration Curve of Vonoprazan Fumarate:**

| Sr.No. | Concentration ug/ml | Absorbance |
|---|---|---|
| 1 | 0 | 0 |
| 2 | 5 | 0.141 |
| 3 | 10 | 0.250 |
| 4 | 15 | 0.339 |
| 5 | 20 | 0.445 |
| 6 | 25 | 0.571 |
| 7 | Slope | 0.022 |
| 8 | Intercept | 0.0156 |
| 9 | Coefficient of Correlation | 0.9959 |

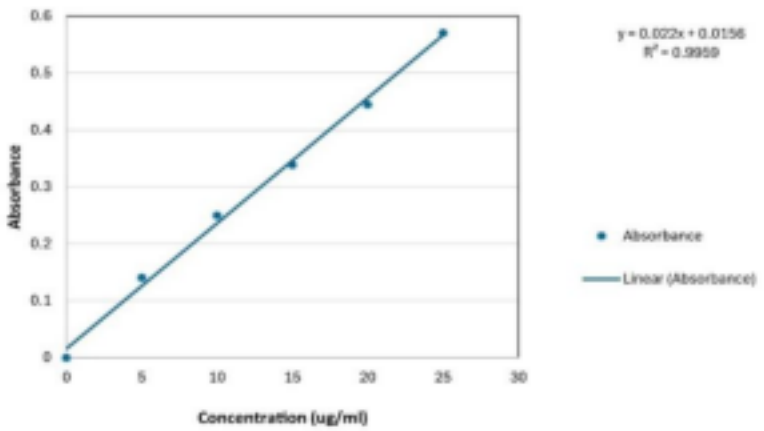


**Fig.No.3.: Calibration Curve of Vonoprazan Fumarate in 0.1 N HCl**

## VI. Spectrocopic Study

**FTIR Spectrum of Vonoprazan Fumarate:**

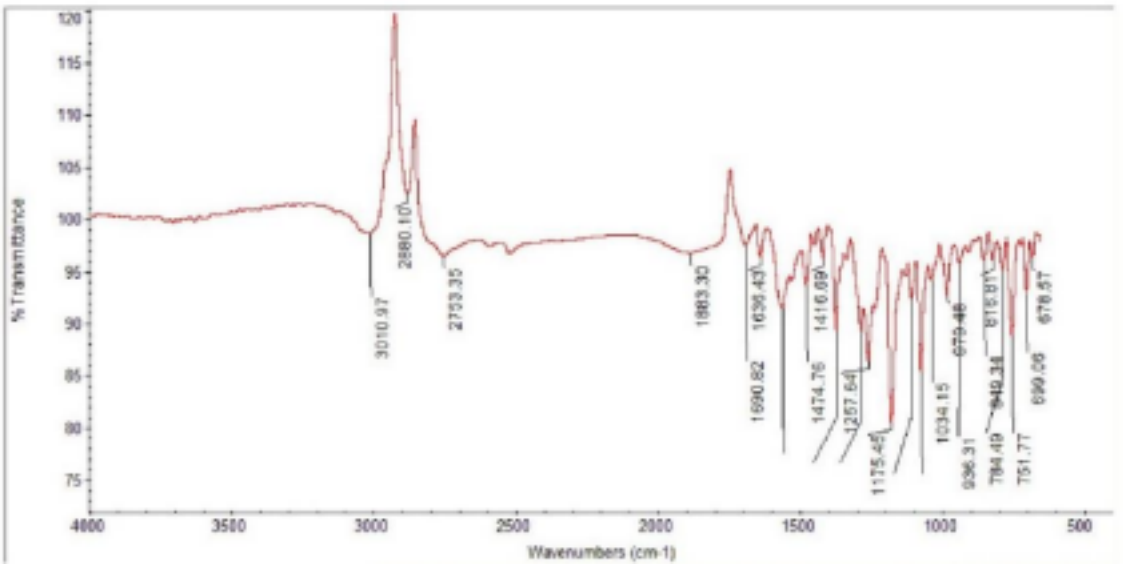


**Fig.No.4: FTIR Spectra of Vonoprazan Fumarate**

**FTIR Spectrum of Blend: (API+ Perlitol SD200+ Crossprovidone)**

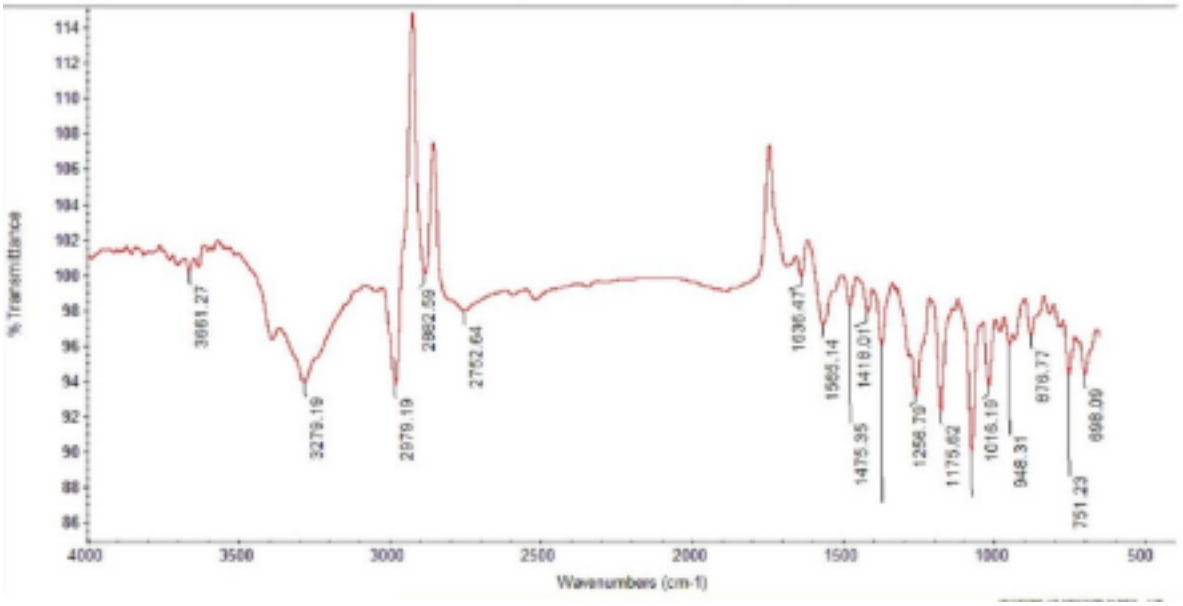


**Fig.No.5: FTIR Spectra of Blend**

## DSC Thermogram –

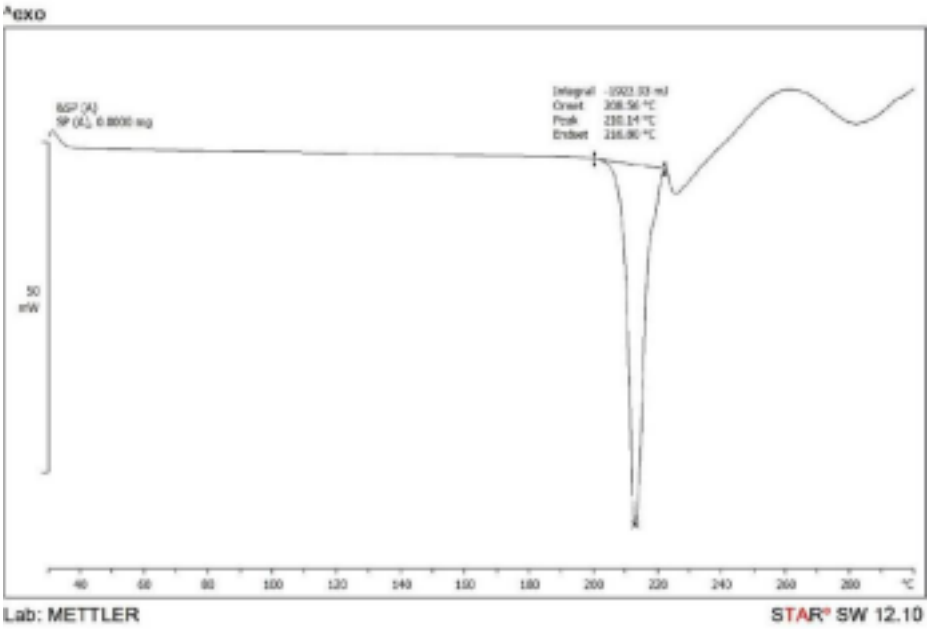


**Fig.No.6: DSC Thermogram of Vonoprazan Fumarat**

## Graphical Representation:

**i. Response Drug Release**

**ii. Response Disintegration:**

## VII. Stability Studies

**Product Name – Vonoprazan Fumarate Chewable Tablet**

**Table No.9: Stability Data for VF1 Optimized batch of Vonoprazan Fumarate Chewable Tablet**

| **Parameters** | | **Condition $40^0 \pm 2°C$ / 75 ± 5% RH** | | | |
|---|---|---|---|---|---|
| | | **Initial** | **1 Month** | **2 Month** | **3Month** |
| **Organoleptic** | Color | Smooth pink tablets | NC | NC | Nc |
| | Odour | Peppermint | NC | NC | NC |

| | | | | | |
|---|---|---|---|---|---|
| | Taste | Sweet peppermint taste | NC | NC | NC |
| **Physical** | Average Weight(mg) | 249.33± 0.6 7 | 249.33± 0.6 7 | 249.21± 0.6 1 | 249.15± 0.6 3 |
| | Thickness (mm) | 4.33±0.01 | 4.33±0.01 | 4.33±0.01 | 4.32±0.01 |
| | Hardness(kg/cm$^2$) | 4.3±0.01 | 4.3±0.01 | 4.2±0.01 | 4.2±0.01 |
| | Disintegration Time(min) | 15 | 15 | 16 | 16 |
| | Friability(%) | 0.41±0.01 | 0.41±0.01 | 0.41±0.01 | 0.42±0.01 |
| **Chemical** | %Drug Release | 97.22 | 97.22 | 97.10 | 97 |
| | Drug Content | 98.10 | 98 | 97.95 | 97.84 |

## VIII. Conclusion

Chewable tablets of were successfully formulated and evaluated for improved patient compliance and ease of administration. The drug showed good linearity at 267 nm with an $R^2$ value of 0.9878, confirming the suitability of the analytical method. All formulations exhibited satisfactory pre-compression and post-compression parameters within acceptable limits.

Among all batches, formulation V1 showed the best performance with 97.22% drug release within 60 minutes and a disintegration time of 15 minutes. The optimized formulation demonstrated acceptable hardness, low friability, good stability, and effective drug release. Therefore, chewable tablets of Vonoprazan Fumarate can be considered a promising alternative dosage form for the treatment of acid-related disorders such as and .

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