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Review

# Development & Characterization of Fast Dissolving Tablet of Vanoprazone

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## Abstract

The present study focuses on the formulation and evaluation of fast dissolving tablets (FDTs) of Vonoprazan using the direct compression method. Various superdisintegrants Sodium Starch Glycolate (SSG), Crospovidone, and Croscarmellose Sodium were incorporated at different concentrations to optimize disintegration and drug release. Select formulations included subliming agents (camphor or menthol) and were subjected to vacuum drying to enhance porosity and dissolution efficiency. All tablets were assessed for pre- and post-compression parameters including thickness, weight variation, hardness, friability, wetting time, dispersion time, disintegration time, drug content, and in vitro release. Among the formulations, VFDT6 (SSG-based) demonstrated superior performance with rapid disintegration, high drug content, low friability, and consistent mechanical strength. VFDT7 (Ac-Di-Sol-based) exhibited the highest cumulative drug release at 300 seconds. Overall, VFDT6 was identified as the most promising candidate for further development, combining rapid onset, physical robustness, and formulation stability.

**Keywords:** Vonoprazan, Fast dissolving tablets, Direct compression, Super-disintegrants, In vitro drug release

## Introduction:

Acid-related gastrointestinal disorders, including gastroesophageal reflux disease (GERD), peptic ulcer disease, and Helicobacter pylori–associated gastritis, are among the most prevalent chronic conditions worldwide and significantly impact patients' quality of life.[1] Effective management of these disorders depends on rapid and sustained suppression of gastric acid secretion. Conventional proton pump inhibitors (PPIs), though widely used, exhibit limitations such as delayed onset of action, variability in acid suppression

due to cytochrome P450 metabolism, and reduced effectiveness under certain physiological conditions.[2] These drawbacks highlight the need for alternative therapeutic agents and improved drug delivery systems that can provide faster symptom relief, consistent efficacy, and enhanced patient compliance.

Vonoprazan is a novel potassium-competitive acid blocker (P-CAB) that inhibits gastric $H^+/K^+$-ATPase in a reversible and potassium-competitive manner.[3] Unlike PPIs, vonoprazan does not require acid activation and provides rapid, potent, and sustained acid suppression from the first dose. Its superior pharmacodynamic profile, longer duration of action, and reduced inter-individual variability make it a promising option for the treatment of acid-related disorders.[4] However, conventional solid oral dosage forms of vonoprazan may present challenges such as delayed disintegration, slower onset of action, and difficulty in swallowing, particularly in pediatric, geriatric, and dysphagic patients.[5]

Fast dissolving tablets (FDTs) have emerged as an effective oral drug delivery system designed to disintegrate and dissolve rapidly in the saliva without the need for water.[6] These dosage forms offer several advantages, including rapid onset of action, improved patient convenience, enhanced bioavailability, and better treatment adherence. The rapid disintegration of FDTs allows for quicker drug release and absorption, which is especially beneficial for drugs intended for prompt therapeutic action.[7] Moreover, FDTs are particularly suitable for patients who experience difficulty swallowing conventional tablets, thereby broadening the scope of oral drug administration.

The formulation of fast dissolving tablets requires careful selection of superdisintegrants and excipients to achieve optimal mechanical strength, rapid disintegration, acceptable taste, and uniform drug release.[8] Superdisintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate promote rapid tablet breakup by mechanisms including swelling, wicking, and deformation recovery.[9] Proper formulation design and processing techniques are essential to ensure tablet stability, content uniformity, and reproducible performance.

The present study focuses on the preparation and characterization of fast dissolving tablets of vonoprazan with the aim of achieving rapid disintegration, prompt drug release, and improved patient compliance. Tablets were formulated using suitable superdisintegrants and excipients through an appropriate manufacturing method. The prepared formulations were systematically evaluated for physicochemical parameters such as weight variation, hardness, friability, drug content uniformity, wetting time, in vitro disintegration time, and dissolution behavior.[10] Stability studies were also conducted to assess formulation robustness and storage stability. Overall, this study aims to establish an optimized fast dissolving tablet formulation of vonoprazan that offers rapid onset of action, improved therapeutic efficacy, and enhanced patient acceptability.

**Materials:**

All the chemicals used in the present study were of analytical grade. Vonoprazan was procured from Spark Analytical, Hyderabad, India. Sodium starch glycolate, crospovidone, croscarmellose sodium, microcrystalline cellulose, polyvinylpyrrolidone (PVP-K30), magnesium stearate, and talc were obtained from S.D. Fine Chemicals, India. These materials were used as received without any further purification.

**Methodology:**

**Formulation of Fast Dissolving Tablet of Vonoprazan**

The formulation of fast dissolving tablets (FDTs) of Vonoprazan was carried out by the direct compression method using various superdisintegrants such as Sodium Starch Glycolate (SSG), Crospovidone, and Croscarmellose Sodium in different concentrations. All the ingredients were passed through a No. 100 mesh sieve to obtain a uniform particle size and to ensure homogeneity. The accurately weighed quantities of Vonoprazan and excipients were mixed thoroughly in a glass mortar and pestle to obtain a uniform blend. The powder mixture was then lubricated with 2% w/w magnesium stearate and 2% w/w talc to improve flow properties and prevent sticking during compression. The final blend was compressed into tablets using a single-punch tablet compression machine (Cadmach, Ahmedabad, India) fitted with flat-faced punches. For selected formulations containing a subliming agent (e.g., camphor or menthol), tablets were subjected to vacuum drying (30 kPa) at 50°C for 6 hours to remove the subliming agent, thereby creating a porous structure to enhance disintegration. The prepared

Vonoprazan FDTs were stored in airtight containers and evaluated for various pre-compression and post-compression parameters to ensure uniformity, strength, and rapid disintegration characteristics.[11]

**Evaluation of Fast Dissolving Tablet of Vonoprazan**

**Thickness:**

The thickness of twenty randomly selected tablets was measured using a digital vernier caliper. The average thickness and standard deviation were calculated to ensure uniformity, which helps in maintaining consistent tablet weight and appearance.[12]

**Hardness:**

Tablet hardness was determined using a Monsanto hardness tester. Six tablets from each formulation were tested, and the average hardness was expressed in kg/cm². Adequate hardness ensures mechanical strength while maintaining the ability to disintegrate rapidly.[13]

**1. Friability Test:**

Ten tablets from each batch were accurately weighed and placed in a Roche friabilator. The friabilator was operated at 25 rpm for 4 minutes (100 revolutions). The tablets were dedusted and reweighed. The percentage weight loss (friability) was calculated, and tablets with less than 1% weight loss were considered acceptable.[14]

**2. Weight Variation Test:**

To assess weight variation, the individual weight (WI) of 20 tablets was determined using an electronic balance. The average weight (WA) was calculated, and the percentage deviation for each tablet was computed using the formula:

**% weight variation = (WA – WI) × 100 / WA**

As per IP (1996), for tablets weighing 120 mg, a ±7.5% deviation is allowed for not more than two tablets. According to USP (2004), a ±10% variation is permissible for not more than two tablets out of twenty.[15]

**3. Wetting Time:**

Wetting time was measured by placing a folded tissue paper (12 cm × 10.75 cm) in a Petri dish (ID = 6.5 cm) containing 6 mL of Sorenson's buffer (pH 6.8). A tablet was placed on the paper, and the time required for complete wetting was recorded. Wetting time indicates the speed of liquid uptake by the tablet and correlates with disintegration efficiency.[16]

**4. In Vitro Dispersion Time:**

The dispersion time of the tablets was measured by placing a tablet in a glass cylinder containing 6 mL of Sorenson's buffer (pH 6.8). Six tablets were tested randomly from each formulation, and the time taken for complete dispersion was recorded.[17]

**5. Drug Content:**

To determine the uniformity of drug content, ten tablets were weighed and finely powdered. A quantity of powder equivalent to 100 mg of Vonoprazan was transferred into a 100 mL volumetric flask containing 70 mL of 0.1N HCl and shaken for 1 hour on a mechanical shaker to ensure complete dissolution. The solution was filtered through Whatman filter paper No. 1 and diluted to volume with 0.1N HCl. From this solution, 1 mL was further diluted to 50 mL with the same solvent, and the absorbance was measured at the λmax of Vonoprazan using a UV-visible spectrophotometer against blank.Drug content was calculated using a calibration curve, and formulations containing 90–110% of the labeled amount were considered acceptable.[18]

**6. Disintegration Time:**

A modified disintegration test was performed to simulate the conditions of the oral cavity. A cylindrical vessel containing a 10-mesh screen was filled with 6 mL of phosphate buffer (pH 6.8) — 4 mL below and 2 mL above the mesh. A tablet was placed on the screen, and the vessel was placed on a shaker. The disintegration time was recorded when no visible residue of the tablet remained on the screen. Six tablets were tested, and the average value was reported.[19]

**Invitro Drug release studies:**

The dissolution profile of Vonoprazan FDTs was studied using USP Type II (paddle) dissolution apparatus at 100 rpm. The dissolution medium consisted of 500 mL of 0.1N HCl (simulating gastric fluid) maintained at 37 ± 0.5°C. At predetermined intervals (1, 2, 5, 10, 15, 20, 30 minutes), 5 mL samples were withdrawn and replaced with fresh dissolution medium. The samples were filtered and analyzed spectrophotometrically at λmax of Vonoprazan to determine the amount of drug released at each interval.Cumulative percentage drug release was plotted against time to evaluate the dissolution behavior of each formulation.[20]

**Result & Discussion:**

**FTIR STUDIES OF VONOPRAZAN DRUG:**

The process of obtaining an infrared spectrum of a solid, liquid, or gas's absorption or emission is known as Fourier-transform infrared spectroscopy, or FTIR. (Figure No:1) High-resolution spectral data over a broad spectral range are concurrently collected by an FTIR spectrometer. Compared to a dispersive spectrometer, which measures intensity over a limited range of wavelengths at a time, this offers a substantial benefit.

**FTIR Study**

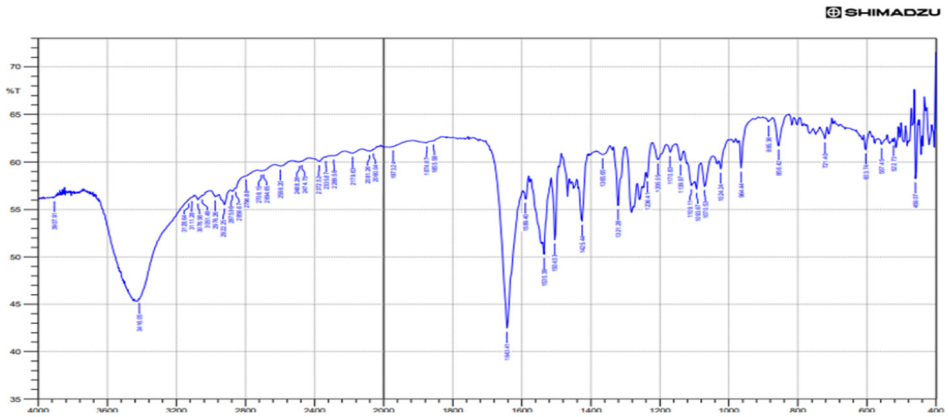


Figure No:1 FTIR of Vonoprazan

**Table No: 1 Formulation Table**

| **Formulation** | **VFDT 1** | **VFDT 2** | **VFDT 3** | **VFDT 4** | **VFDT 5** | **VFDT 6** | **VFDT 7** | **VFDT 8** | **VFDT 9** |
|---|---|---|---|---|---|---|---|---|---|
| Vonoprazan (mg) | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Sodium Saccharine(mg ) | 47 | 39 | 31 | 47 | 39 | 31 | 47 | 39 | 31 |
| Cross povidone(mg) | 8 | 16 | 24 | - | - | - | - | - | - |
| SSG(mg) | - | - | - | 8 | 16 | 24 | - | - | - |
| Ac-Di-Sol(mg) | - | - | - | - | - | - | 8 | 16 | 24 |
| Magnesium stearate(mg) | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Total weight(mg) | **100** | **100** | **100** | **100** | **100** | **100** | **100** | **100** | **100** |

**VFDT=** ***Vonoprazan Fast Dissolving Tablet***

**Table No: 2 Characterization of Vonoprazan Fast dissolving tablets**

| Formulation | Thickness(mm) | Weight variation (%) | Hardness(kg/cm2) | Friability |
|---|---|---|---|---|
| **VFDT1** | 3.06 | 1.89 | 5.12 | 0.321 |
| **VFDT2** | 3.02 | 1.91 | 5.23 | 0.421 |
| **VFDT3** | 3.05 | 1.87 | 5.27 | 0.432 |
| **VFDT4** | 3.04 | 1.90 | 5.31 | 0.471 |
| **VFDT5** | 3.11 | 1.88 | 5.26 | 0.512 |
| **VFDT6** | 3.04 | 1.16 | 5.32 | 0.253 |
| **VFDT7** | 3.07 | 1.92 | 5.48 | 0.782 |
| **VFDT8** | 3.01 | 1.88 | 5.44 | 0.861 |
| **VFDT9** | 3.02 | 1.95 | 5.55 | 0.751 |

The physical characterization of Vonoprazan Fast Dissolving Tablets (VFDTs) demonstrates (Table No: 2) consistent manufacturing quality across all formulations, with thickness ranging narrowly between 3.01 mm and 3.11 mm. Weight variation remains within acceptable pharmacopeial limits, with VFDT6 exhibiting the highest uniformity (1.16%). Hardness values span from 5.12 to 5.55 kg/cm², indicating adequate mechanical strength for handling and packaging. Friability results show VFDT6 as the most robust formulation (0.253%), while VFDT8 and VFDT9 approach the upper acceptable threshold, suggesting a need for further optimization. Overall, VFDT6 combines excellent uniformity, strength, and minimal friability, reinforcing its suitability for fast-dissolving tablet development.

**Table No: 3 Characterization of Vonoprazan Fast dissolving tablets**

| Formulation | Wetting time(sec) | Dispersion Time(sec) | Disintegration Time(sec) | Drug Content (%) |
|---|---|---|---|---|
| **VFDT1** | 220 | 182 | 200 | 92 |
| **VFDT2** | 110 | 98 | 101 | 91 |
| **VFDT3** | 100 | 84 | 96 | 94 |
| **VFDT4** | 112 | 80 | 114 | 93 |
| **VFDT5** | **103** | **82** | **125** | **96** |
| **VFDT6** | 96 | 52 | 100 | 98 |
| **VFDT7** | 99 | 74 | 132 | 94 |
| **VFDT8** | 103 | 78 | 123 | 92 |
| **VFDT9** | 105 | 62 | 118 | 91 |

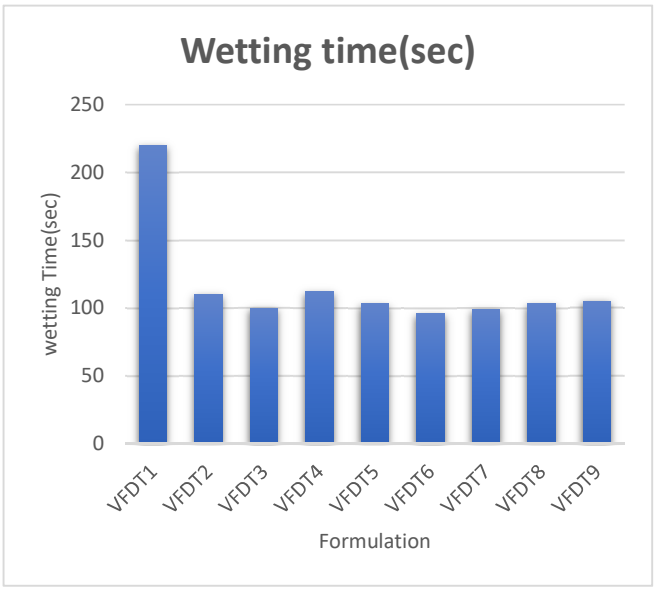


Figure No:2(a) Wetting time(sec)

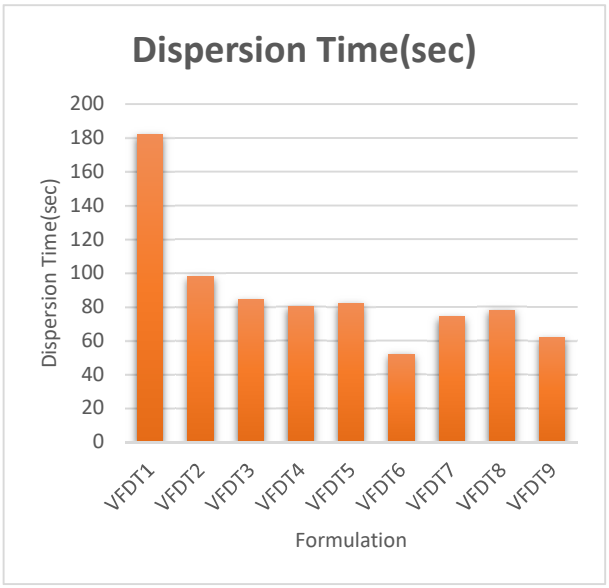


Figure No:2(b) Dispersion Time(sec)

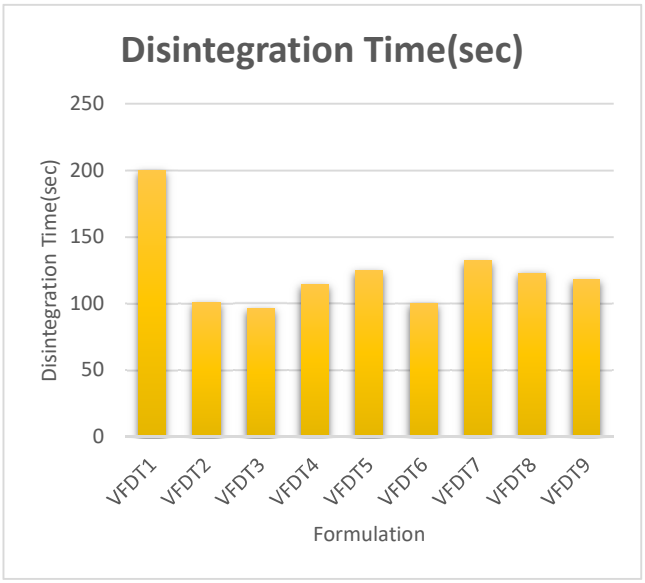


Figure No:2(c) Disintegration Time(sec)

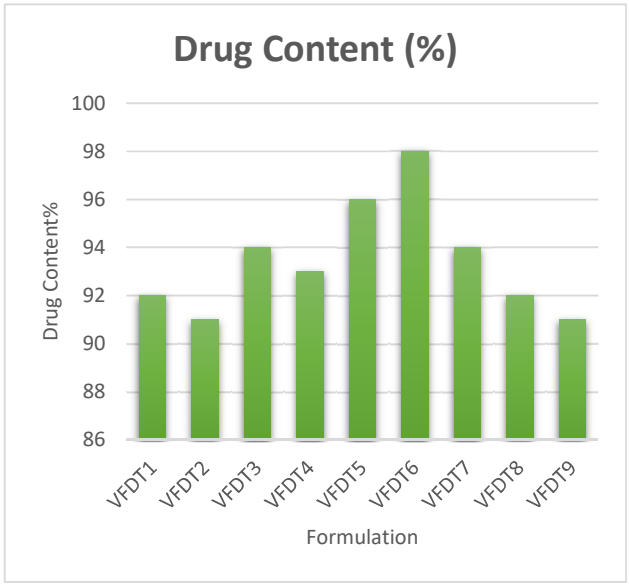


Figure No:2(d) Drug Content (%)

The characterization of Vonoprazan Fast Dissolving Tablets (VFDTs) reveals (2a, 2b, 2c, 2d) significant variation across formulations in terms of wetting time, dispersion time, disintegration time, and drug content. Among the nine formulations tested, VFDT6 demonstrated superior performance with the shortest wetting time (96 sec), fastest dispersion (52 sec), and rapid disintegration (100 sec), coupled with the highest drug content (98%). These attributes

suggest VFDT6 offers the most efficient onset of action and optimal drug delivery, making it the most promising candidate for further development. In contrast, VFDT1 exhibited the longest times across all parameters, indicating the need for reformulation to enhance its dissolution profile. Overall, the data supports VFDT6 as the lead formulation for fast-dissolving tablet development.

**Table No: 4 In vitro Release study of VFDT**

| Time(sec) | CROSSPOVIDONE | VFDT1 | VFDT2 | VFDT3 | SSG | VFDT4 | VFDT5 | VFDT6 | Ac Di SOL | VFDT7 | VFDT8 | VFDT9 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | | 0 | 0 | 0 | | 0 | 0 | 0 | | 0 | 0 | 0 |
| 10 | | 24.21 | 23.75 | 22.20 | | 23.21 | 21.24 | 22.94 | | 24.24 | 23.57 | 21.41 |
| 20 | | 35.21 | 32.21 | 30.22 | | 39.67 | 30.20 | 31.69 | | 39.65 | 36.24 | 32.76 |
| 30 | | 51.21 | 48.46 | 47.21 | | 51.24 | 47.21 | 43.69 | | 50.85 | 48.36 | 45.25 |
| 60 | | 57.25 | 60.25 | 50.86 | | 56.64 | 60.48 | 50.48 | | 54.34 | 65.86 | 50.35 |
| 90 | | 62.45 | 66.25 | 57.47 | | 61.25 | 68.54 | 56.27 | | 59.24 | 68.45 | 58.21 |
| 180 | | 68.12 | 76.68 | 62.24 | | 69.27 | 74.24 | 61.37 | | 68.35 | 74.21 | 65.58 |
| 300 | | 79.16 | 78.24 | 71.54 | | 79.57 | 77.56 | 72.25 | | 82.25 | 77.15 | 69.69 |

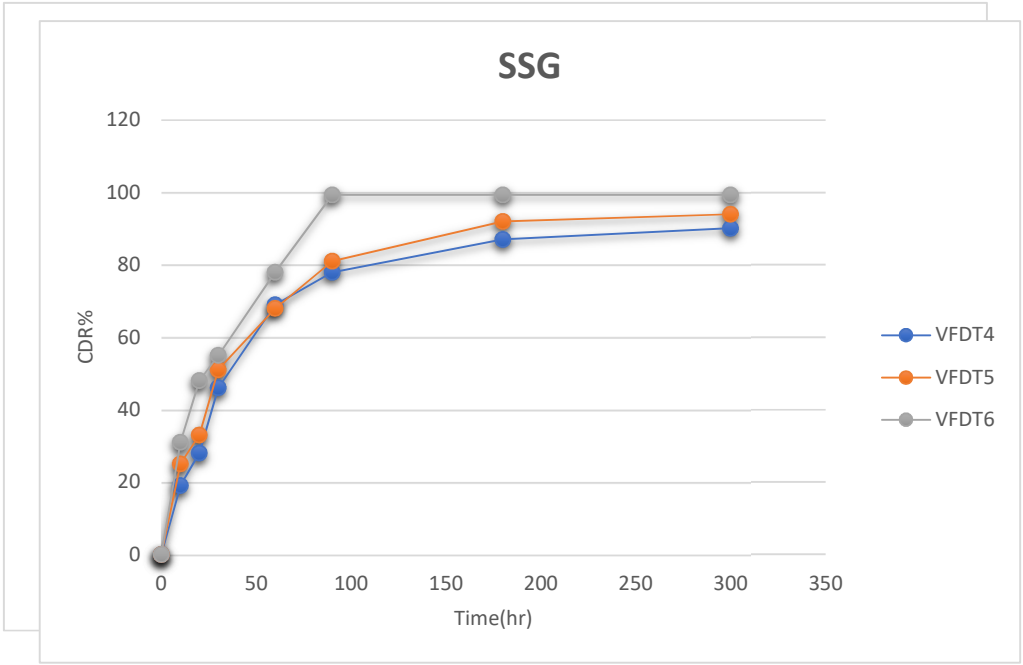


Figure No:3(a) CDR % of Crosspovidone

Figure No:3(b) SSG

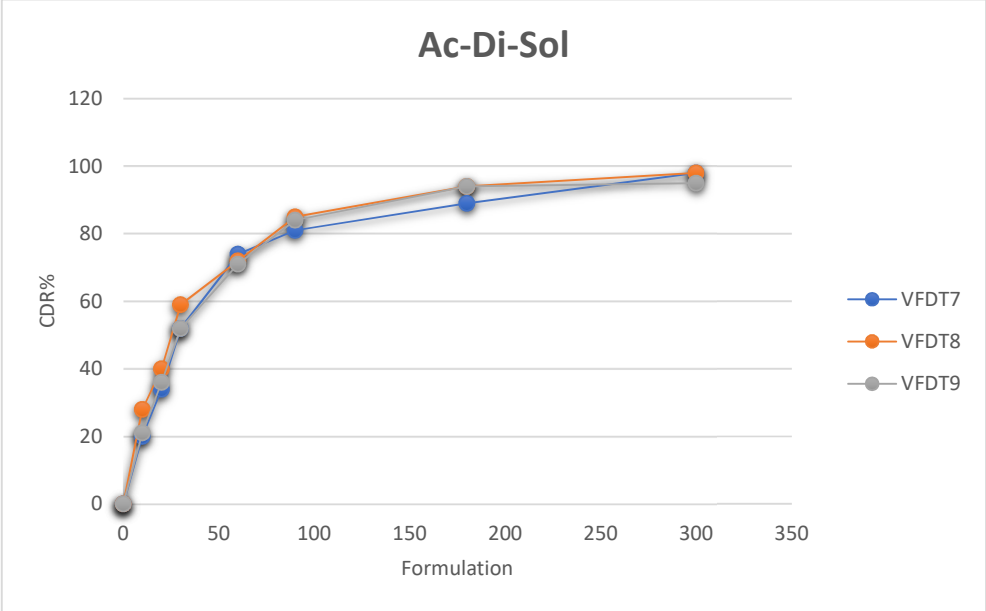


Figure No:3(c) Ac-Di-Sol

The in vitro release study of Vonoprazan Fast Dissolving Tablets (VFDTs) was conducted (3a, 3b, 3c) across three excipient groups—Cross Povidone (VFDT1–VFDT3), Sodium Starch Glycolate (VFDT4–VFDT6), and Ac-Di-Sol (VFDT7–VFDT9)—to evaluate drug release profiles over time. All formulations exhibited zero release at 0 seconds, confirming baseline integrity. By 10 seconds, initial release ranged from 21.41% to 24.24%, indicating rapid onset across all groups.

Among the Cross Povidone group, VFDT1 showed the highest cumulative release at 300 seconds (79.16%), followed closely by VFDT2 (78.24%) and VFDT3 (71.54%). In the Sodium Starch Glycolate group, VFDT4 and VFDT5 reached 79.57% and 77.56% respectively, while VFDT6 achieved 72.25%. The Ac-Di-Sol group demonstrated slightly lower release rates, with VFDT7 reaching 82.25%, VFDT8 at 77.15%, and VFDT9 at 69.69%.

Overall, VFDT7 (Ac-Di-Sol) exhibited the highest drug release at 300 seconds, suggesting superior disintegration and dissolution efficiency. VFDT6 (SSG) also performed well, balancing rapid release with robust physical characteristics. These findings support VFDT7 and VFDT6 as lead candidates for further optimization and clinical evaluation.

**Table No: 5 Release Kinetic Data**

| Formulation code | Zero order | First order | Higuchi | Peppas | Drug release mechanism |
|---|---|---|---|---|---|
| | R2 | R2 | R2 | N | |
| **VFDT1** | 0.977 | 0.978 | 0.970 | 0.681 | Non-fickian |
| **VFDT2** | 0.948 | 0.992 | 0.974 | 0.681 | Non-fickian |
| **VFDT3** | 0.905 | 0.992 | 0.989 | 0.552 | Non-fickian |
| **VFDT4** | 0.966 | 0.985 | 0.984 | 0.653 | Non-fickian |
| **VFDT5** | 0.928 | 0.985 | 0.992 | 0.550 | Non-fickian |

| | | | | | |
|---|---|---|---|---|---|
| **VFDT6** | 0.881 | 0.994 | 0.992 | 0.485 | Non-fickian |
| **VFDT7** | 0.918 | 0.991 | 0.989 | 0.569 | Non-fickian |
| **VFDT8** | 0.99 | 0.986 | 0.987 | 0.521 | Non-fickian |
| **VFDT9** | 0.873 | 0.985 | 0.987 | 0.446 | Fickian |

## Conclusion:

In order to improve tablet disintegration and drug release, different superdisintegrants were added to the formulation of fast-dissolving vonoprazan tablets used in this study. Vonoprazan is a poorly water-soluble medication with an aqueous solubility of about 20 µg/mL, high lipophilicity (log P = 3.97), and relatively low oral bioavailability (about 56%). This is mainly because of its extensive hepatic first-pass metabolism and poor dissolution characteristics that correspond to Biopharmaceutics Classification System (BCS) Class II drugs. Because of these physicochemical constraints, an optimized formulation strategy must be developed in order to enhance oral absorption and dissolution behavior.

Numerous physicochemical parameters were assessed for each prepared vonoprazan fast-dissolving tablet. Studies on weight variation showed consistent tablet weights with low standard deviation values, suggesting good content uniformity. The tablet formulations' hardness was found to be between 4 and 5 kg/cm², indicating sufficient mechanical strength. All formulations showed friability below 1%, indicating adequate mechanical stability, with friability values ranging from 0.50% to 0.75% (Table 2). The drug content analysis revealed a percent drug content between 97.3% and 99.1%, with low standard deviation values, suggesting that the drug was distributed uniformly throughout the tablets.

To look into potential interactions between vonoprazan and the formulation's excipients, Fourier Transform Infrared (FT-IR) spectroscopy was employed. Amine stretching at 3303.78 $cm^{-1}$, aromatic C–H stretching at 2933.83 $cm^{-1}$, aliphatic C–H stretching at 2850.86 $cm^{-1}$, carboxylic (COOH) stretching at 2801.6 $cm^{-1}$, carbonyl (C=O) stretching at 1684.52 $cm^{-1}$, C–N stretching at 1210.51 $cm^{-1}$, and ether linkage stretching at 1147.6 $cm^{-1}$ were the distinctive peaks in the FT-IR spectrum of pure vonoprazan. The spectra of the physical mixtures containing various grades of polymers and excipients retained these distinctive peaks, suggesting that there were no notable drug–excipient interactions.

To clarify the mechanism of drug release, kinetic modeling using zero-order, first-order, Higuchi, and Korsmeyer-Peppas equations was applied to the in vitro drug release data of all vonoprazan formulations (F1–F9). The results of the linear regression analysis and the associated regression coefficients were computed and tabulated. All formulations were found to follow first-order release kinetics based on the regression coefficient values ($r^2$ ranging from 0.9000 to 0.965). Drug release from formulations FRM1–FRM8 and FRM10–FRM11 primarily occurred via a non-Fickian diffusion mechanism, while formulations FRM9 and FRM12 followed a Fickian diffusion mechanism, according to Higuchi and Korsmeyer–Peppas model analysis. Formulations FRM13 and FRM14 also showed non-Fickian diffusion, whereas FRM15 showed Fickian diffusion behavior. This suggests that the polymer properties and formulation composition had an impact on the release mechanism.

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