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DESIGN AND ASSESSMENT OF FAST RELEASE TABLETS OF VONOPRAZAN

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ABSTRACT

The formulation design discloses Vonoprazan fast-release tablets, to be used for treating various types of acid-related diseases. The tablet formulation uses various compatible excipients (like diluents, binders, disintegrants, glidants, and lubricants) by the wet granulation method. The fast-releasing tablet of Vonoprazan is rapid dissolution and absorption of the drug, bioavailability is high, may give rapid onset of action, and the intestinal residual is few, and hence few side effects. The bitter taste of Vonoprazan fumarate is masked with film-coating, this is expected to improve patient compliance. Vonoprazan fumarate does not require acid activation to bind to the proton pump. It is acid-stable and does not require an enteric coating to protect from acid degradation in the stomach. FTIR studies revealed that the drug was compatible with excipients, which were used in the formulation. In the present study film coated fast release tablet was developed because it is acid-stable and bitter taste. Accelerated stability study of selected optimized formulations was done as per ICH guidelines for 3 months at 40±2ºC/ 75±5% RH, which revealed that formulations V1 & V8 have no significant change with respect to the initial characteristics observed.

Keywords

Vonoprazan fumarate, Potassium Competitive Acid Blocker, acid-related disease, fast-release tablets, disintegrants, and wet granulation technique.

1. INTRODUCTION

The drug delivery system must provide the drug at a rate determined by the needs of the body during the treatment period[1]. Solid pharmaceutical dosage forms provide convenience and ease of administration, greater flexibility in the design of the dosage form, ease of production and low cost.

Gastric acid secretion is a complex process, that involves neurons, hormones, and endocrine pathways, and all have a common target- parietal cells. Parietal cells secrete concentrated hydrochloric acid into the gastric lumen. Acids cause the onset and continuation of gastroesophageal reflux disease, upper gastrointestinal damage associated with NSAIDs, and hypersecretion ulcerations such as Zollinger-Ellison Syndrome[2].

Fast Release Tablet

The form of fast-release enables the dissolution of drugs without the intention of retarding or prolonging their dissolution or absorption, which is a result of the change in the drug's pharmacokinetic parameters. The instantaneous release of drugs from rapid-release granules leads to a sudden increase in blood concentration[3].

Significance of fast-release tablet:

- ❖ The drug dissolves rapidly and is absorbed quickly, causing a rapid onset of action,
- ❖ Develop a fast-release tablet to achieve rapid release in the GIT, which can improve absorption and improve the bioavailability of therapy.

Potassium Competitive Acid Blocker (P-CAB)

Vonoprazan fumarate reversibly inhibits the activity of hydrogen-potassium adenosine triphosphate (H^+/ K^+ ATPase), reducing the secretion of gastric acid 350 times more than the standard PPIs[4].

Vonoprazan is rapidly absorbed following oral administration, with a median time of peak plasma concentrations (t_{max}) typically occurring within 2 hours after once-daily dosing. The rate of elimination from the plasma allows for once- or twice-daily dosing, with mean elimination half-life ($t_{1/2}$) values of 7 to 8 hours[5].

Mechanism of Action:

Vonoprazan fumarate is the fumarate salt of Vonoprazan, a pyrrole derivative and a reversible potassium competitive acid inhibitor, with potent antacid activity[6]. Vonoprazan is not required to be activated by acid and it prevents acid secretion by competitively blocking the potassium-binding site of gastric H^+/K^+ -ATPase, a key enzyme in the process of gastric acid secretion[7]. The blocks the activation of the H^+/K^+ ATPase by K^+ inhibits the proton pump, prevents gastric acid secretion, and reduces gastric acid levels[8].

2. MATERIALS AND METHODS

Material

Vonoprazan fumarate, Mannitol, MCC PH101, Hydroxypropyl Cellulose, Starch, Croscarmellose sodium, Sodium Starch Glycolate, Crospovidone, Colloidal Silicon Dioxide, Purified Talc, Sodium Stearyl fumarate etc. are provided by Biogain Remedies Pvt. Ltd., Rupandehi, Nepal.

Machine

All manufacturing machines and equipment like Weighing Balance, Vibro sifter, Mass mixer, Tray dryer, Double Cone Blender, Digital Tapped Density Apparatus, Single Rotary Compression Machine-16 Station,

Digital Vernier Caliper, Digital Hardness Tester, Friabilator, R&D Mini Coater, Alu-Alu Packaging Machine etc. are used of Biogain Remedies Pvt. Ltd.

Equipment

All testing facilities and equipment like Analytical Weighing Balance, FTIR Spectrophotometer, Moisture Balance, Magnetic Stirrer, Digital Vernier Caliper, Digital Hardness Tester, Friabilator, pH Meter, UV Spectrophotometer, Disintegration Testing Apparatus, Automatic Dissolution Test Apparatus, HPLC, Leak Test Apparatus, Real-Time Stability Chamber (Walk-in), Accelerated Time Stability Chamber, etc. are used of Biogain Remedies Pvt. Ltd.

Drug Excipient Compatibility Study[9, 10]:

Incompatibility can cause changes in the physical, chemical, microbiological, or therapeutic properties of the dosage form. The binary mixtures of the drug with the excipients being investigated were closely mixed in the ratio of 1:1 and were placed into clear, natural glass ampoules, and a rubber stopper was placed on the vial, and sealed properly. Studies were conducted in glass vials at accelerated conditions, 40°C ± 2°C / 75% RH ± 5% RH for a storage period of 4 weeks. After storage, the sample was compared to the control at 2-8°C and observed physically for liquefaction, caking, and discolouration. Thus it was concluded that the excipients selected for the formulation were compatible with Vonoprazan fumarate.

FORMULATION OF VONOPRAZAN FAST RELEASE TABLETS

Fast-release tablets of Vonoprazan (20mg) were prepared through the wet granulation method as per the composition shown (formulation codes, V1 to V8) in the table:

Table No.2.1 Composition of Vonoprazan 20mg tablets

S. No.	Materials	V1	V2	V3	V4	V5	V6	V7	V8
1	Vonoprazan fumarate	26.72	26.72	26.72	26.72	26.72	26.72	26.72	26.72
2	Mannitol	110	110	110	110	110	110	110	110
3	MCC PH101	33.28	23.28	33.28	23.28	33.28	23.28	33.28	23.28
4	Hydroxypropyl Cellulose	5	5	5	5	5	5	5	5
5	Purified water	45	45	45	45	45	45	45	45
6	Dry Starch	20	30						
7	Croscarmellose Sodium			4	10				
8	Sodium Starch Glycolate					4	10		
9	Crospovidone							4	10
10	Aerosil 200	1	1	1	1	1	1	1	1

11	Purified Talc	2	2	2	2	2	2	2	2
12	Sodium Stearyl fumarate	2	2	2	2	2	2	2	2
Uncoated Tablet (mg)		**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**

Method

All the raw materials were dispensed as per the formulation sheet. Vonoprazan, Mannitol and MCC PH101 were passed through a 60 mesh screen prior to mixing. HPC dissolved in water to prepare the binding solution. The powder mixer granulates with the binder and dries. After dry sizing the granules with 20 mesh screens. Lubrication the granules with lubricants which were already passed through 60 mesh screens. The lubricated blend was evaluated for pre-compressional parameters and compress tablet. After compression tablets were evaluated for post compressional parameters. Prepare coating solution and the tablets were coated with a film coat of up to 5mg per tablet.

3. RESULTS AND DISCUSSION

Evaluation of API (Vonoprazan fumarate)

Table No.3.1 Organoleptic Properties of Vonoprazan fumarate

Test	**Specification**	**Observation**
Colour	White to off-white powder	White to off-white powder
Odour	Characteristic odour	Characteristic odour
Taste	Bitter taste	Bitter taste

Table No.3.2 Determination of compressibility index and flow properties

Bulk Density (g/ml)	**Tapped Density (g/ml)**	**Angle of repose**	Compressibility Index	Hausner's Ratio	**Flow Property**
0.480±0.031	0.749±0.022	47.93±1.057	35.78±5.747	1.56±0.134	Very poor

±SD, n=3

The organoleptic characteristics of the API (i.e. Vonoprazan fumarate) comply with in-house specifications. The obtained results indicated that it has very poor flow properties for compression, therefore tablet manufacturing preferred the wet granulation method.

Determination of λmax of Vonoprazan fumarate by UV Spectrophotometric method:

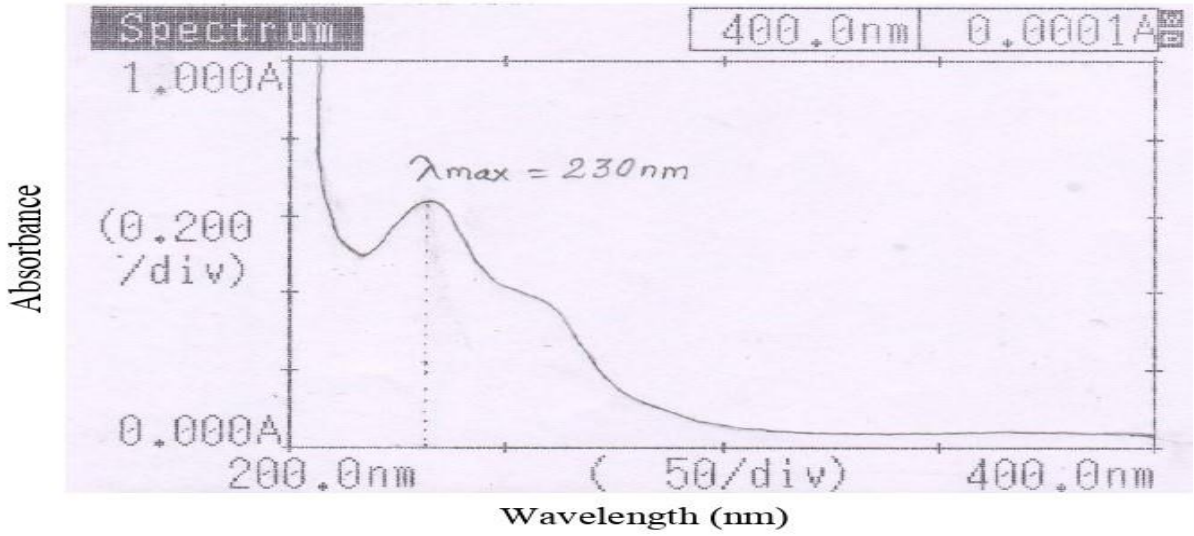


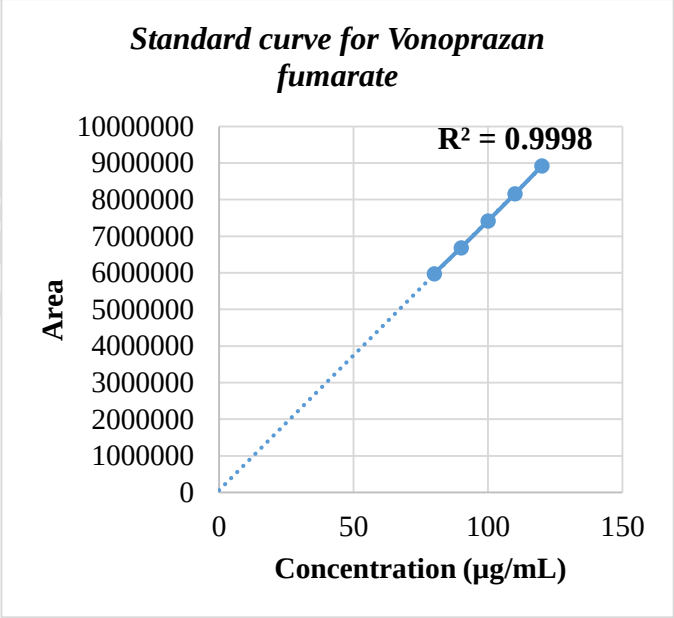
Fig. No.3.1 λmax scan for Vonoprazan fumarate

A spectrum of the working standard is obtained by scanning from 200-400nm against the reagent blank to fix absorption maxima. The λmax was found to be **230nm**. Hence standard curve, drug content, and dissolution testing are being carried out at the same wavelength[11].

Calibration (Standard) Curve for Vonoprazan fumarate

Standard solution (Linearity): The calibration curve was plotted by preparing various concentrations of Vonoprazan fumarate in diluent {water (75)**:** Acetonitrile (25)}.

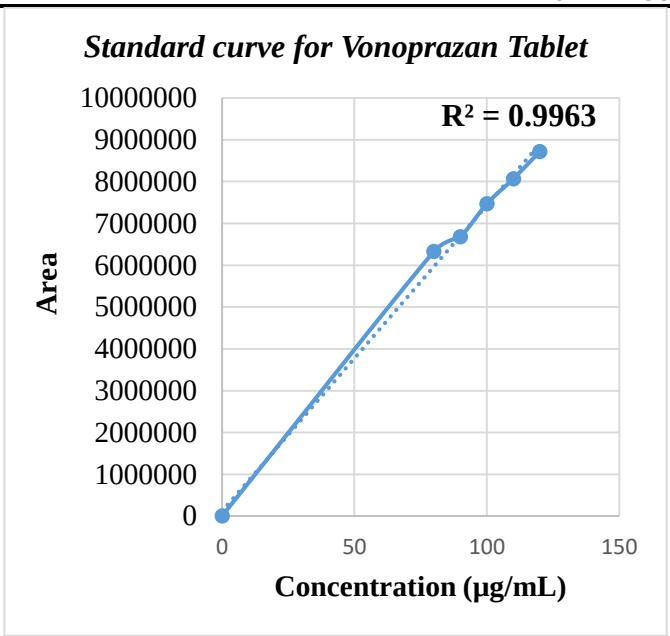
S. No.	Concentration (µg/mL)	Area
1.	0	0
2.	80	5975034
3.	90	6684327
4.	100	7417530
5.	110	8159105
6.	120	8925339



Graph No.3.1 Standard curve for Vonoprazan fumarate (Linearity)

Test solution (Range): The calibration curve was plotted by preparing various concentrations of Vonoprazan tablet in diluent {water (75)**:** Acetonitrile (25)}.

S. No.	Concentration (µg/mL)	Area
1.	0	0
2.	80	6325720
3.	90	6680820
4.	100	7467441
5.	110	8065411
6.	120	8715984



Graph No.3.2 Standard curve for Vonoprazan Tablet (Range)

Drug-excipient interaction studies by FTIR

IR spectra matching approach was used for the detection of any possible chemical reaction between the drug and the excipients. A physical mixture (1:1) of drug and excipients was prepared and mixed with a suitable quantity of potassium bromide. It was scanned from 4000 to 150 cm^{-1}in a Shimadzu FTIR Spectrophotometer. The IR spectrum of the physical mixture was compared with those of pure drugs and excipients and matching was done to detect any appearance or disappearance of peaks.

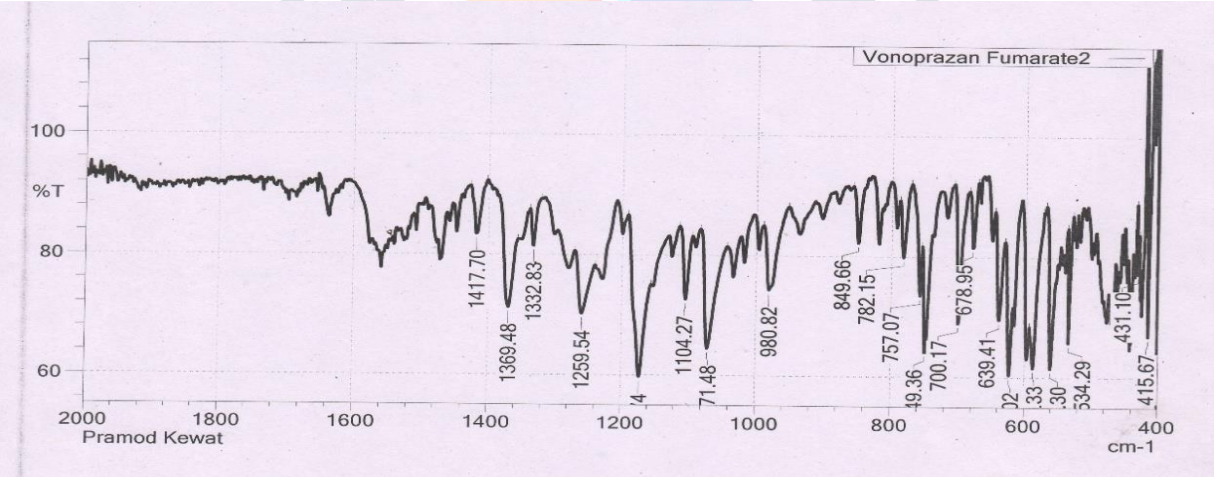


Fig. No.3.2 FTIR Spectra of Vonoprazan fumarate

Characterization of Tablets

Evaluation of Pre-compression Parameters

The prepared powder blend was evaluated for pre-compression parameters like angle of repose, bulk density, tapped density, compressibility index and Hausner ratio.

Batch	Derived Properties					
	Bulk Density (g/ml)	Tapped Density (g/ml)	Moisture Content (%)	Angle of Repose (º)	Compressibility Index	Hausner's Ratio
V1	0.466±0.008	0.592±0.013	1.58	38.15±2.725	21.18±0.419	1.27±0.007

V2	0.496±0.007	0.675±0.017	1.77	41.28±2.401	26.47±0.855	1.36±0.016
V3	0.445±0.006	0.557±0.010	1.02	37.69±1.050	20.10±0.281	1.25±0.004
V4	0.436±0.005	0.547±0.007	1.33	33.68±2.384	20.18±0.156	1.25±0.002
V5	0.432±0.004	0.538±0.002	1.38	35.08±2.557	19.81±0.744	1.25±0.012
V6	0.440±0.013	0.551±0.023	1.50	36.66±2.023	20.05±1.999	1.25±0.031
V7	0.428±0.011	0.547±0.015	1.32	36.44±2.586	21.75±0.687	1.28±0.011
V8	0.427±0.006	0.554±0.006	1.56	37.00±2.764	22.82±0.277	1.30±0.005

±SD, n=3

The angle of repose is a characteristic of the internal friction or cohesion of the particles and the value of the angle of repose will be high if the powder is cohesive and low if the powder is non-cohesive. The range of angle of repose for all the formulations is 33.68 to 41.28^{o}, which indicates that the flow of the granules ranges from poor to fair.

The range of Carr's index for all the formulations is 19.81 to 26.47% and Hausner's ratio is 1.25 to 1.36, which indicates that the flow of the granules ranges from poor to fair. The flow property plays an important role in the pharmaceuticals especially in the tablet formulation because improper flow may cause more weight variation.

Evaluation of Vonoprazan Tablets (Post-Compression Parameters)

The prepared tablets were evaluated for weight variation, thickness, hardness, friability, disintegration time, drug content, and *in-vitro* dissolution studies.

Batch	Weight variation(mg)	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Disintegration Time (min.)	Drug Content (%)
V1	202.83±1.602	3.26±0.015	10.93±0.181	0.18±0.179	1min. 40sec.	103.20±0.071
V2	204.00±2.098	3.33±0.015	11.12±1.005	0.41±0.059	1min. 52sec.	105.62±0.530
V3	201.50±2.074	3.26±0.046	14.73±0.796	0.25±0.072	7min. 55sec.	95.94±0.552
V4	202.83±1.722	3.30±0.025	12.13±0.834	0.27±0.053	3min. 32sec.	102.30±0.354
V5	202.50±2.345	3.22±0.034	15.34±0.914	0.29±0.031	4min. 35sec.	99.16±0.502
V6	201.33±1.211	3.24±0.010	10.72±0.566	0.28±0.047	3min. 15sec.	101.16±0.163
V7	200.00±3.688	3.26±0.023	15.18±2.227	0.30±0.016	4min. 22sec.	99.98±0.028
V8	201.50±1.378	3.30±0.037	11.57±0.400	0.28±0.067	1min. 12sec.	100.77±0.679

±SD, n=6

General Appearance

The overall appearance, visual identity, and "elegance" of tablets are essential for consumer acceptance. The tablet must be free of cracks, depressions, pinholes, etc.

Weight Variation

The weight variation for all the formulated tablets was found to be as per the criteria mentioned in the IP 2018.

Diameter

The diameter of all the formulated tablets is maintained at a constant value of 8mm and the thickness of the tablets was found to be in the range of 3.22 to 3.33mm and are within the limits of the standard deviation.

Hardness

Hardness (diametric crushing strength) is the force needed to break the tablet through the diameter. It is an indication of its strength. The tablet must be stable to mechanical stress during handling and transportation. The hardness of all the formulated tablets was found to be in the range of 10.72 to 15.34 Kg/cm^2. It indicates all the tablets have adequate mechanical strength.

Friability

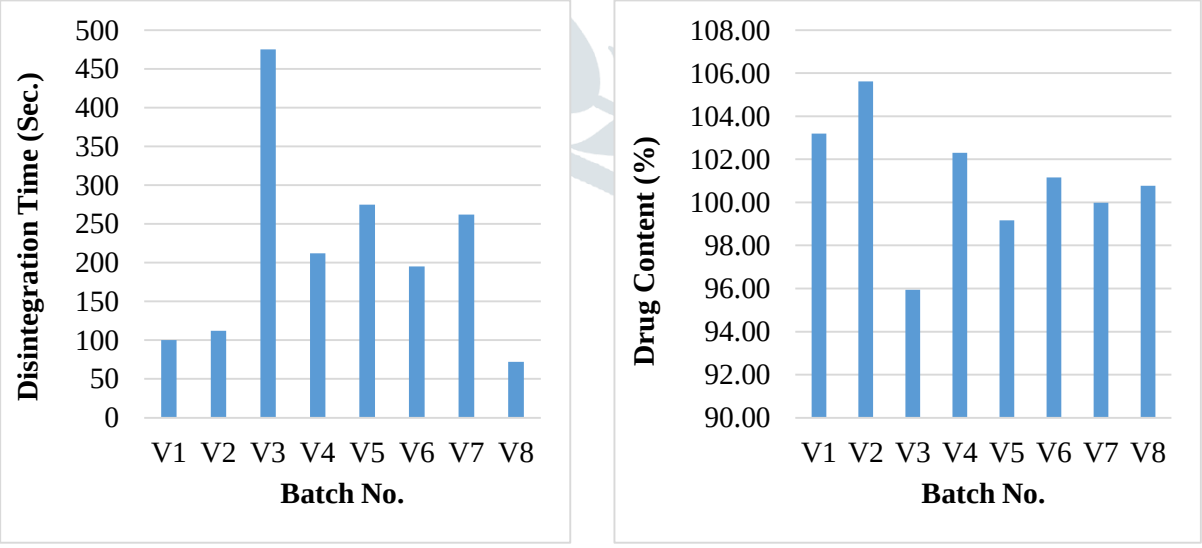
The test is applied to compressed tablets and aims to determine the physical strength of tablets. ***Roche friabilator*** is used to measure the friability of the tablets. The friability of all the formulated tablets is within the limits (NMT 1%) along with the standard deviation in limit.

Disintegration Time

This test determines whether dosage forms such as tablets, capsules, etc. Disintegrate within the specified time when placed in a liquid medium under the specified experimental conditions. The disintegration time of all the formulated uncoated tablets is within the limits (NMT 15min).

Drug Content

The assay of Vonoprazan tablets was found to be in the range of 95.94 to 105.62%. The acceptable limit of the drug content as per specification is 90-110%. The results reveal that the say of Vonoprazan was within the acceptable limits.



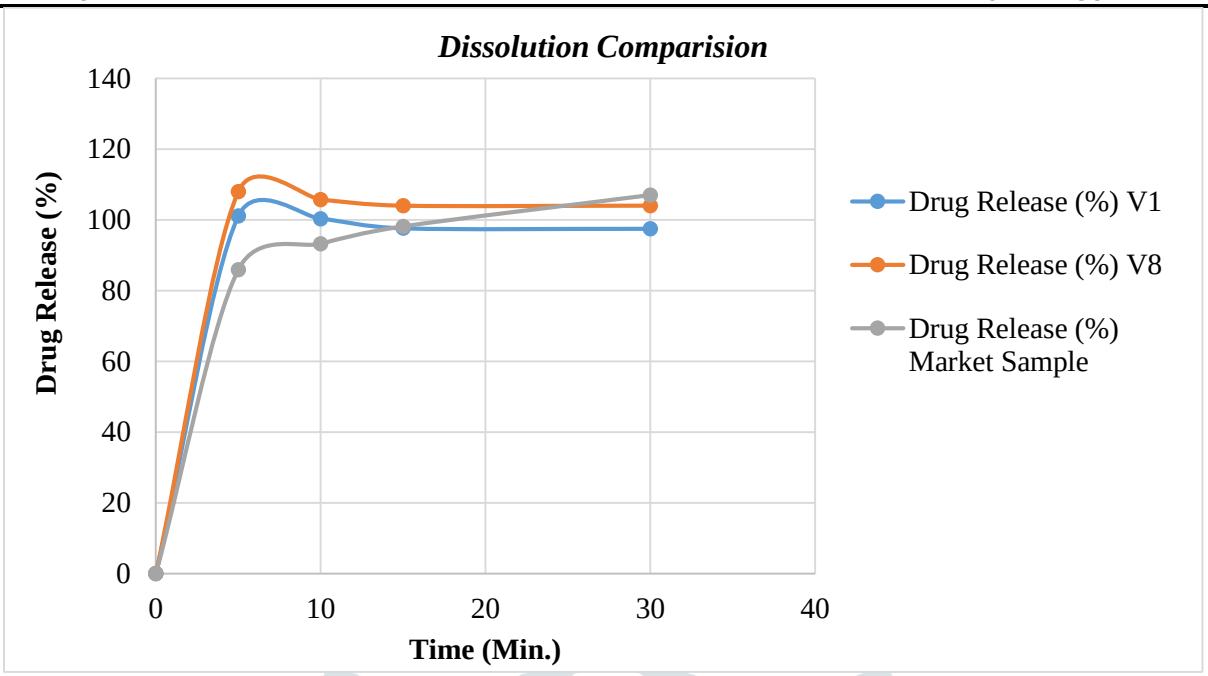
Graph No.3.3 Disintegration time and Percentage drug content of different batches

IN-VITRO RELEASE (DISSOLUTION) PROFILE OF THE FORMULATIONS

Batch	Time (min.)	Dissolution (%)						
		S1	S2	S3	S4	S5	S6	Average
V1	5min.	101.98	99.30	103.63	99.03	101.55	101.06	101.09±1.726

	10min.	100.53	98.27	102.59	98.88	100.63	101.12	100.34±1.563
	15min.	98.15	96.20	96.20	97.38	98.41	99.51	97.64±1.309
	30min.	96.04	94.68	96.04	95.67	101.55	101.06	97.51±2.988
V2	5min.	125.02	118.98	124.64	116.40	130.77	115.70	121.92±5.884
	10min.	120.28	115.96	133.95	122.44	124.85	118.42	122.65±6.338
	15min.	118.24	116.95	124.18	117.33	111.77	128.52	119.50±5.930
	30min.	110.99	120.14	123.42	126.45	108.27	108.55	116.30±8.015
V3	5min.	76.88	80.10	80.65	78.84	77.92	87.58	80.33±3.812
	10min.	94.82	87.13	82.50	97.48	80.12	85.44	87.92±6.870
	15min.	85.44	88.54	90.77	82.18	84.33	90.12	86.90±3.437
	30min.	80.84	91.75	78.41	85.27	84.36	87.58	84.70±4.752
V4	5min.	108.75	102.31	103.80	100.89	103.11	102.17	103.51±2.750
	10min.	107.48	100.89	102.57	99.91	102.23	100.96	102.34±2.698
	15min.	98.98	105.78	100.69	98.01	99.84	99.09	100.40±2.785
	30min.	100.09	93.86	95.17	93.04	95.10	93.93	95.20±2.530
V5	5min.	84.68	78.20	80.40	81.99	77.99	85.45	84.45±3.174
	10min.	80.84	81.75	78.41	85.27	84.36	87.58	83.04±3.325
	15min.	87.78	84.35	88.45	80.64	83.33	86.42	85.16±2.957
	30min.	91.28	88.45	90.68	92.00	87.24	93.33	90.50±2.268
V6	5min.	102.5	96.38	99.80	101.04	102.02	97.18	99.82±2.542
	10min.	110.22	108.69	105.21	105.39	106.27	110.27	107.68±2.346
	15min.	109.35	105.88	101.43	100.88	106.64	108.74	105.49±3.596
	30min.	104.04	107.11	102.72	100.49	105.94	109.32	104.94±3.176
V7	5min.	87.77	81.98	80.33	85.00	81.92	73.80	81.80±4.735
	10min.	87.50	90.10	82.65	90.84	83.92	87.58	87.10±3.265
	15min.	97.11	87.99	94.52	90.78	87.60	84.52	90.42±4.698
	30min.	101.40	99.48	97.55	86.40	92.80	89.24	94.48±5.965
V8	5min.	109.24	106.90	108.10	108.31	108.41	107.06	108.00±0.884
	10min.	104.87	104.36	105.66	106.69	107.93	105.02	105.76±1.333
	15min.	103.79	102.18	104.16	105.10	107.28	101.71	104.04±2.029
	30min.	106.22	102.75	103.40	104.75	104.24	102.92	104.05±1.313
Voniza (B.No. 145822)	5min.	87.25	86.92	84.18	85.88	82.77	88.52	85.92±2.120
	10min.	95.55	94.14	93.42	96.45	90.27	89.55	93.23±2.790
	15min.	99.54	100.11	97.77	98.78	92.48	100.20	98.15±2.921
	30min.	104.58	109.85	109.42	104.65	107.58	105.92	107.00±2.318

±SD, n=6



Graph No.3.4 Comparative In-vitro dissolution for Vonoprazan V1 & V8 with market sample Voniza

The formulations V1 and V2 were manufactured with Starch as disintegrants with 10 & 15% w/w respectively. The formulation was tested for its release properties and found to be drug release of formulation V1 uniform within the limits of the standard deviation. However, formulation V2 was more released with a deviation more than the limit.

The formulations V3 and V4 were manufactured with Croscarmellose Sodium as disintegrants with 2 & 5% w/w respectively. The formulation was tested for its release properties and found to be a drug release of formulation V3 at a lower limit (**NLT 80% (Q)** of the stated amount of Vonoprazan) However, the formulation V4 was uniform and optimum range.

The formulations V5 and V6 were manufactured with Sodium Starch Glycolate as disintegrants with 2 & 5% w/w respectively. The formulation was tested for its release properties and found to be drug release of formulation V5 at a lower limit, However, formulation V6 was uniform and optimum range.

The formulations V7 and V8 were manufactured with Crospovidone as disintegrants with 2 & 5% w/w respectively. The formulation was tested for its release properties and found to be drug release of formulation V7 at a lower limit, However, formulation V8 was uniform and optimum range.

The results revealed that the drug released from the marketed product was fairly matching with the drug released from the tablet formulations V1 & V8.

STABILITY STUDY[12]

The purpose of stability testing is to produce evidence on how the quality of a drug substance or drug product varies with time under the effects of various environmental factors including temperature, humidity, light, and recommended storage conditions, shelf half-life to be established. The tablets were packed in Alu-Alu blister

and stored in a stability chamber at accelerated conditions like 40±2ºC/ 75±5%RH for a period of 3 months and evaluated for any liable changes in the description, weight variation, thickness, hardness, drug content and in-vitro dissolution at specified intervals of every month.

Stability study of the formulation V1:

Evaluation Parameters	**Initial (0M)**	***Storage condition: 40±2ºC/ 75±5% RH***		
		1M	**2M**	**3M**
Description	Peach, round, biconvex, film-coated tablets with plain smooth surfaces on both sides.	Complies	Complies	Complies
Weight variation (mg)	205.33±1.033	205.80±1.042	206.02±1.024	206.48±1.052
Thickness (mm)	3.30±0.015	3.30±0.022	3.32±0.021	3.33±0.024
Hardness (Kg/cm^2)	12.53±0.171	12.42±0.511	11.18±0.602	8.10±0.582
Drug content (%)	102.16±1.351	102.75±0.918	101.01±1.782	100.65±0.757
Dissolution (%)	97.51±2.988	99.11±2.033	100.27±2.432	96.12±0.875

Stability study of the formulation V4:

Evaluation Parameters	**Initial (0M)**	***Storage condition: 40±2ºC/ 75±5% RH***		
		1M	**2M**	**3M**
Description	Peach, round, biconvex, film-coated tablets with plain smooth surfaces on both sides.	Complies	Complies	**Brownish colour** core of the tablet
Weight variation (mg)	206.83±1.472	208.30±1.142	209.02±1.124	212.48±1.012
Thickness (mm)	3.35±0.031	3.46±0.154	3.54±0.184	3.60±0.027
Hardness (Kg/cm^2)	14.07±0.447	12.42±0.402	10.18±0.112	6.50±0.142
Drug content (%)	99.67±0.552	99.08±1.280	96.51±1.452	93.73±0.578
Dissolution (%)	95.20±2.530	100.82±2.070	92.54±1.280	88.70±1.280

Stability study of the formulation V6:

Evaluation Parameters	**Initial (0M)**	***Storage condition: 40±2ºC/ 75±5% RH***		
		1M	**2M**	**3M**
Description	Peach, round, biconvex, film-coated tablets with plain smooth surfaces on both sides.	Complies	Complies	**Tablet became soft**
Weight variation (mg)	207.00±2.366	208.14±2.142	208.92±2.118	210.24±2.165
Thickness (mm)	3.30±0.020	3.50±0.154	3.56±1.450	3.62±0.877
Hardness (Kg/cm^2)	13.31±0.979	12.11±1.360	10.88±0.118	7.20±0.172

Drug content (%)	99.98±0.516	99.40±0.410	94.37±0.997	91.76±1.125
Dissolution (%)	104.94±3.176	107.00±1.984	95.92±2.142	90.18±0.997

Stability study of the formulation V8:

Evaluation Parameters	**Initial (0M)**	***Storage condition: 40±2ºC/ 75±5% RH***		
		1M	**2M**	**3M**
Description	Peach, round, biconvex, film-coated tablets with plain smooth surfaces on both sides.	Complies	Complies	Complies
Weight variation (mg)	206.33±1.633	206.74±0.102	207.08±2.004	208.24±0.185
Thickness (mm)	3.42±0.027	3.48±0.154	3.51±2.860	3.52±0.799
Hardness (Kg/cm^2)	13.43±1.185	15.11±1.630	14.14±2.036	12±0.184
Drug content (%)	101.36±0.636	100.75±0.495	100.85±0.636	99.04±0.339
Dissolution (%)	104.05±1.313	101.45±1.904	98.22±2.087	97.68±1.984

Initially among all the formulations V1, V4, V6 and V8 were found to be uniform drug release within the limits of the standard deviation. However, formulation V2 was more released and V3, V5, and V7 were released at a lower limit i.e. NLT 80% (Q).

The stability studies are carried out for the formulations V4 and V6. There is no physical changes were observed but the weight, and thickness of the tablet gradually increased every month. Decreases in hardness, drug content, and drug release, that is might be due to moisture uptake, which indicates that the formulation V4 and V6 were unstable at the stress conditions.

However, for the formulations V1 and V8. There were no significant changes in the physical characteristics of the tablets, which indicates that the optimized formulations V1 and V8 were stable at the accelerated conditions. The results revealed that the drug released from the marketed product was fairly matching with the drug released from the tablet formulations V1 and V8.

4. CONCLUSION

In the present work, a film-coated tablet of Vonoprazan fumarate has been developed. The objective of the study was to deliver a fast release of Vonoprazan fumarate over an extended period of time up to 24 hrs. and hence reduce the frequency of administration. This was expected to improve clinical efficacy and patient compliance. The tablets were prepared by wet granulation method and analyzed for pre-compression and post-compression test parameters.

Finally, I concluded that formulation V1 & V8 shows the best drug release and drug content and that may fulfil the objective of the study of fast release. Formulation V1 contains 10% of dry starch as disintegrants and formulation V8 contains 5% of super disintegrants i.e. Crospovidone. Among both formulations, starch required a double amount of crospovidone for the same objective of fast release. The final product was correlated with the marketed product.

Formulation and usage of these methods are considered to be safe, without any complication. Therefore, it can be concluded that the film-coated tablet of Vonoprazan fumarate may be one of the novel dosage forms that can revolutionize the pharmaceutical and healthcare sectors.

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