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DEVELOPMENT AND CHARACTERIZATION OF VONOPRAZAN FUMARATE LOADED FLOATING MICROSPONGES

Deepshikha Tiwari[1]*, Dr. Kamlesh Dashora[2], Dr. Praveen Khirwadkar[3]

Institute of Pharmacy, Vikram University, Ujjain, Madhya Pradesh, India-456010.

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***Corresponding Author**
Deepshikha Tiwari
Institute of Pharmacy,
Vikram University, Ujjain,
Madhya Pradesh, India-
456010.

ABSTRACT

Peptic ulcer disease (PUD) is defined by discontinuity in the inner lining of the gastrointestinal (GI) tract caused by gastric acid production or pepsin. It penetrates the muscularis propria layer of the stomach epithelium. It mainly affects the stomach and proximal duodenum. It could affect the lower oesophagus, distal duodenum, or jejunum. Antisecretory drugs used for the treatment of peptic ulcer disease (PUD) include H2-receptor antagonists and proton pump inhibitors (PPIs). Potassium-competitive acid blockers (PCABs), such as vonoprazan, are a new class of acid suppressants that hold great potential for improving the treatment of peptic ulcer diseases. Microsponges are polymeric delivery mechanisms made up of porous microspheres. They are little, sponge-like spherical particles with a large porous surface. Furthermore, they may improve stability, reduce side effects, and optimize drugs release. Microsponges are porous polymeric microspheres that are mostly used for topical applications but have lately been employed for oral delivery. In this research paper we developed and characterised vonoprazan fumarate loaded microsponges. Microsponges drug delivery system can provide extended release of the drug. Ten formulations of floating microsponges were prepared using Eudragit L100 as extended release polymer and ethyl cellulose as a polymer which facilitated buoyancy to the microsponges. Characterization of the microsponge was done on various parameters such as production yield, encapsulation efficiency, particle size analysis, SEM analysis, in vitro dissolution studies with drug release kinetics as well as in vitro buoyancy studies.

KEYWORDS: Microsponges, Vonoprazan fumarate, Peptic Ulcer, Extended Release, Bouyancy.

1. INTRODUCTION

Microsponge delivery systems are uniform, spherical, porous polymeric microspheres having myriad of interconnected voids of particle size range 5-300µm.[1] Microsponges consisting of non collapsible structures with porous surface through active ingredients are released in a controlled manner.[2] The application of microsponges in extended release drug delivery systems is particularly.

Advantageous in managing chronic conditions that require consistent therapeutic levels of medication. By employing various polymers and fabrication techniques, researchers can tailor the properties of microsponges to optimize drug release profiles according to specific clinical needs. Furthermore, the versatility of microsponges allows for the incorporation of a wide range of drugs, including hydrophilic and hydrophobic compounds, making them suitable for diverse therapeutic applications. As research continues to advance in this field, microsponges hold significant promise for enhancing the efficacy and safety of drug therapies.[3]

Vonoprazan Fumarate is a pyrrole derivative and reversible potassium-competitive acid blocker (P-CAB) with possible antacid properties, vonoprazan fumarate is the fumarate salt version of vonoprazan. After being administered, vonoprazan binds to the proton pump of the gastric hydrogen-potassium ATPase (H^+/K^+ ATPase) in a particular and competitive manner at or, most likely, proximal to its potassium ion (K^+) binding site, statically inhibiting K^+ binding. This lowers gastric acid levels by inhibiting the proton pump, blocking the activation of the H^+/K^+ ATPase by K^+, and hindering the release of gastric acid.[4-5] When developing microsponges using the quasi-emulsion solvent diffusion method, vonoprazan fumarate was used as a model drug due to its quicker and complete absorption through the stomach and upper intestine. With high drug loading capacity, microsponges provide an effective drug delivery system for stomach-specific administration. It can incorporate a variety of active ingredients with a high degree of efficiency. The purpose of this research was to develop a controlled delivery system containing drug Vonoprazan fumarate with different ratio of polymer.

2. MATERIALS AND METHODS

Metrochem API Pvt. Ltd. Hyderabad, Telangana, India provided Vonoprazan fumarate as a gift sample. Eudragit L-100 (CDH), Ethyl Cellulose (Qualikems), Polyvinyl Alcohol (Loba Chemie Pvt. Ltd.) and Sodium Chloride (CDH). All the other chemical, reagents and solvents were of analytical grade.

2.1 Pre-formulation Studies

The purpose of the preformulation study was to ensure the accuracy of the drug sample and to determine various parameters for the formulation of microsponges.

2.1.1 Organoleptic properties: Vonoprazan fumarate's physical appearance was evaluated based on a number of organoleptic characteristics, including colour, state, odour, and taste.

2.1.2 Determination of melting point: The capillary fusion method was used to estimate the melting point of the vonoprazan fumarate. A little amount of medication was placed inside a capillary that was sealed at one end, and the capillary was then positioned with the sealed end facing down into the melting point device.

2.1.3 Determination of absorption maxima(λ_{max}) of Vonoprazan fumarate

In a 50 mL volumetric flask, 5 mg drug was precisely weighed and dissolved in 50 mL of 1:1 ratio of Phosphate buffer (20 mM, pH=6.8) and methanol which yielded a stock solution of 100 µg/mL. Now 1ml of stock solution was taken in 10 mL volumetric flask and volume was made upto 10mL with distilled water. A solution of 10 µg/mL concentration was made. Now 1 ml solution was taken from the 10 µg/mL concentration solution in a 10 ml volumetric flask and the volume was made upto 10 mL with distilled water. This yielded a solution of 1 µg/mL concentration. Now this sample solution of 1µg/mL concentration was scanned to get high absorption employing a double beam U.V. visible spectrophotometer at a distance from 200 to 600 nm.[6]

2.1.4 Calibration curve of Vonoprazan fumarate: In a 50 mL volumetric flask, 5 mg drug was precisely weighed and dissolved in 50 mL of previously prepared diluent which yielded a stock solution of 100 µg/mL. Further 0.5 mL, 1 mL, 1.5 mL, 2 mL, 2.5 mL, 3 mL, 3.5 mL, 4 mL, 4.5 mL and 5 mL were taken from this stock solution and transferred to a 10 mL volumetric flask. The volume was then made up to 10 mL with distilled water to get various concentrations of 5, 10, 15, 20, 25, 30, 35, 40, 45 and 50 µg/mL. Using methanol as the reference solution, the absorbance was measured at 260 nm.

2.1.5 Fourier Transform Infra-red Spectral Analysis (FTIR STUDY): For the purpose of identifying qualitative compounds, the sample IR spectra was used. FTIR analysis of the material was performed. The infra red spectrum of Vonoprzan fumarate was performed on

the Fourier Transformed infra-red Spectrophotometer. The sample was scanned at wavelength 4000-400cm^{-1}.[7]

2.1.6 Drug- Polymer Interaction Study: It was crucial to examine the compatibility studies of the medicine and polymers employed within the system when developing microsponges. Method used - between 4000cm^{-1} and 600cm^{-1} , the infrared absorption spectra of the drug, polymer, and mixture of polymer and drug were conducted.

2.2 Formulation: To prepare the inner organic phase, Eudragit L-100 and ethyl cellulose is dissolved in ethanol and dichloromethane. Next, the drug is added to the solution and dissolved under ultrasonication at 35^{o}C. Sodium chloride was used as a porogen in the quasi-emulsion solvent diffusion approach to create the microsponge. After making a 2% (w/v) aqueous solution of the porogen, enough tween 80 was added while stirring to achieve a 1.5% (v/v) dispersion. To create w/o emulsion, the porogen solution was evenly emulsified in polymeric solution. The inner phase is poured into the polyvinyl alcohol solution in water (outer phase). Following 60 minutes of stirring, the mixture is filtered, to separate the microsponges. The microsponges are dried in an air-heated oven at 40 ^{o}C for 12 hours.

Ingredients can be entrapped in microsponge polymers either at the time of synthesis, or if too labile to withstand polymerization conditions, they can be post-loaded after the microsphere structure has been pre-formed.[8-12]

Table 1: Composition of Vonoprazan Fumarate Loaded Microsponges by Quasi Emulsion Solvent Diffusion Method.

Formulation Code	Vonoprazan Fumarate (mg)	Eudragit L-100 (mg)	Ethyl Cellulose (mg)	Ethanol/ DCM (ml)	Sodium Chloride (%w/v)	Polyvinyl Alcohol (%w/v)
MS 1	20	100	300	20	2	0.5
MS 2	20	100	600	20	2	0.5
MS 3	20	100	900	20	2	0.5
MS 4	20	100	300	20	2	1.0
MS 5	20	100	600	20	2	1.0
MS 6	20	100	900	20	2	1.0
MS 7	20	100	300	20	2	1.0
MS 8	20	100	600	20	2	1.5
MS 9	20	100	900	20	2	1.5
MS 10	20	100	750	20	2	1.5

2.3 Characterization of microsponges

2.3.1 Determination of Production Yield: Calculating the beginning weight of raw materials and the end weight of microsponges will produce the percentage yield. The following formula can be used to determine percentage yield[13]:

$$\text{Production yield} = \frac{\text{Practical mass of microsponges}}{\text{Theoritical mass of (polymer+drug)}} \times 100$$

2.3.2 Determination of Drug Content and Encapsulation Efficiency: Vonoprazan fumarate loaded microsponges that were weighed and placed to a volumetric flask containing distilled water in 10 ml were kept in a water bath shaker for 20 min. at 35°C. following proper dilutions, filtered, and spectrophotometric test at 230 nm. Utilizing the following formula, the medication content and encapsulation effectiveness were determined[13-14]:

$$\text{Drug content} = \frac{\text{Practical drug content}}{\text{Theoretical drug content}} \times 100$$

$$\text{Loading efficiency} = \frac{\text{Actual drug content of microsponges}}{\text{Theoritical drug content}} \times 100$$

2.3.3 Analysis of morphology and surface topography of microsponges (SEM): SEM analysis of prepared microsponges was carried by using Scaaning Electron Microscopy (SEM) Model: EVO 18, Make: Carl Zeiss. The surface morphology of the improved microsponge formulation was studied using scanning electron microscopy. Using double-sided adhesive tape, the sample was placed directly onto the SEM sample holder, and images were captured using a scanning electron microscope at various magnifications and an acceleration voltage of 5 kV.[15]

2.3.4 Particle Size Analysis and Zeta Potential Analysis: Particle size analysis and Zeta potential analysis of prepared microsponges was carried by using NanoPlus-3 with Nanoplus AT. Microsponges were dispersed in double distilled water before running sample in the instrument, to ensure that the light scattering signal, as indicated by particles count per second, was within instrument's sensitivity range. During the measurement, particles are passed through a focused laser beam. These particles scatter light at an angle that is inversely proportional to their size. The angular intensity of the scattered light is then measured by a series of photosensitive detectors. The map of scattering intensity versus angle is the primary source of information used to calculate the particle size.

2.3.5 In- vitro Release Studies: After adding 900 mL of pH-1.2, 0.1N HCl to the vessel, the USP basket apparatus was put together. At a temperature of 37°C ± 0.5 °C, the medium was allowed to equilibrate. The capsules were filled with prepared microsponges powder, put in the vessel, and spun at 50 rpm for 12 hours. 5 ml of the receptor fluid were taken out, filtered, and then reintroduced at predetermined intervals. Using the dilution media, the samples were diluted appropriately, and they were then examined spectrophotometrically at 230 nm.[16-17]

2.3.6 In vitro Buoyancy Studies: Spread across the surface of 100 mL of 0.1N HCl pH 1.2 with 0.02 percent (w/v) tween 80 was used for the prepared microsponges. To promote gastric fluid, use tween 80. For 8 hours, the mixture was stirred magnetically at 100 rpm speed and 37ºC±0.5ºC for 8 h. At a predefined time point, every percentage of microsponges that were floating on the surface and those that had settled down were collected. After drying, the collected samples were weighed. The following equation was used to calculate the percent buoyancy.[18-20]

% Buoyancy = weight of microsponges floating on the surface / initial total weight of microsponges×100

2.3.7 Stability Studies: Formulation code MS9 was packed in capsule at room temperature (75% RH and 40 °C). At 30, 60 and 90 days, the capsules were assessed for assay and dissolution profile testing.

3. RESULTS

3.1 Pre-formulation Studies

3.1.1 Determination of physicochemical properties

The physicochemical properties of vonoprazan fumarate were found to be -

Table 2: Interpretation of physicochemical properties of Vonoprazan fumarate.

Sr. No.	Physical Parameters	Interpretation
1.	Colour	White
2.	Odour	Odourless
3.	Taste	Bitter
4.	State	Crystalline powder

3.1.2 Determination of melting point

The temperature at which a substance transitions from its solid to liquid state under a single atmosphere of pressure is known as the melting point of that substance. The drug's purity is implied by the melting point determination. The capillary fusion methos was used to

determine the melting point of Vonoprazan fumarate, and it was discovered to be remarkably similar to the reported melting point provided in table no.3.

Table 3: Melting Point Of Vonoprazan Fumarate.

Method Employed	Literature Value	Experimental Value
Capillary Fusion Method	203-209 ^{o}C	203-204 ^{o}C

3.1.3 Determination of absorption maxima(λ_{max}) of Vonoprazan fumarate

Chromophoric molecules in solution absorb light of a certain wavelength when exposed to light in the visible/ultraviolet portion of the spectrum, depending on the type of electronic transition involved in the absorption. The primary application of ultraviolet visible spectroscopy is quantitative analysis, and it is a helpful adjunct tool for understanding the structural makeup of many medications. The UV spectrum is typically depicted as a wavelength versus absorbance diagram.

The maximum wavelength of Vonoprazan fumarate was observed to be 229 nm which is found to be similar with reference standards.

Table 4: Absorption maxima(λ_{max}) of Vonoprazan fumarate.

Name of the Solvent	Absorption maxima (λ_{max})	Standard Absorption maxima (λ_{max})
1:1 ratio of Phosphate buffer (20 mM, pH=6.8) and methanol	229 nm	230 nm

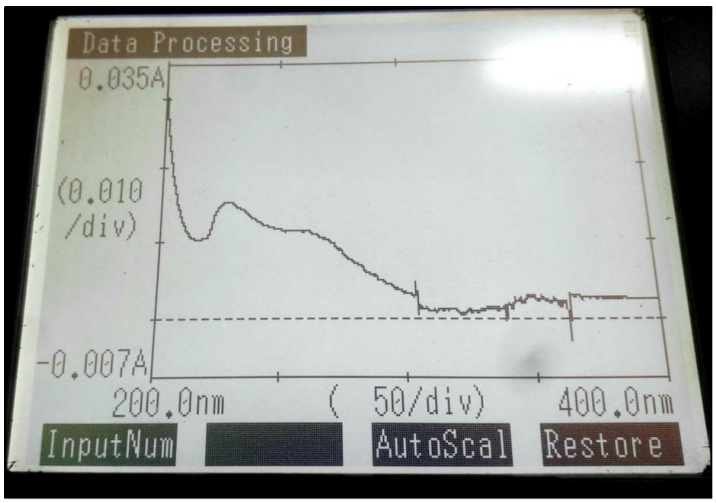

Fig. 1: Absorption maxima(λmax) of Vonoprazan fumarate.

3.1.4 Calibration Curve of Vonoprazan Fumarate

Vonoprazan fumarate in previously prepared diluent yield characteristics curve when scanned in the UV range between 200-400 nm. The λmax for Vonoprazan fumarate was found at 230 nm. Different concentrations of Vonoprazan fumarate in the range 5-50 µg/mL were analyzed spectrophotometrically to obtain their respective absorbance.

Table 5: Calibration curve data of vonoprazan fumarate.

Sr. No.	Concentration (µg/mL)	Absorbance
1.	0	0
2.	5	0.312
3.	10	0.459
4.	15	0.608
5.	20	0.818
6.	25	1.124
7.	30	1.326
8.	35	1.666
9.	40	1.704
10.	45	1.969
11.	50	2.255

The calibration curve of the drug follows Beer's Lambert law. The calibration curve was shown in fig. 2.

Table 6: Statistical parameters related to calibration curv.

Sr. No.	Parameter	Value
1.	Regression Coefficient	0.9933
2.	Intercept	0.01
3.	Equation of Line	y = 0.441x+0.01

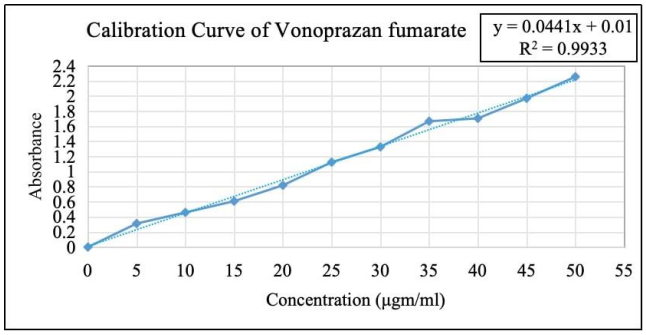

Fig. 2: Calibration Curve of Vonoprazan Fumarate.

3.1.5 Fourier Transform Infra-red Spectral Analysis (FTIR STUDY)

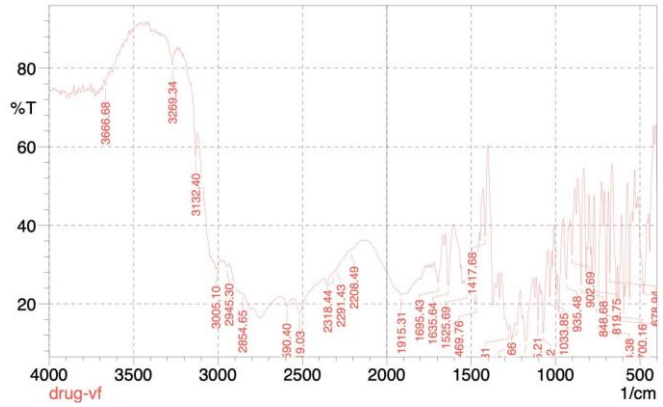

Fig. 3: FTIR Spectra Of Drug Vonoprazan Fumarate.

3.1.6 Drug- Polymer Interaction Study: The characteristic peak of the drug in the IR spectra that was retained in the mixture did not physically change during the drug-excipient interaction under study. This shows that there is no incompatibility between the drug and the excipient.

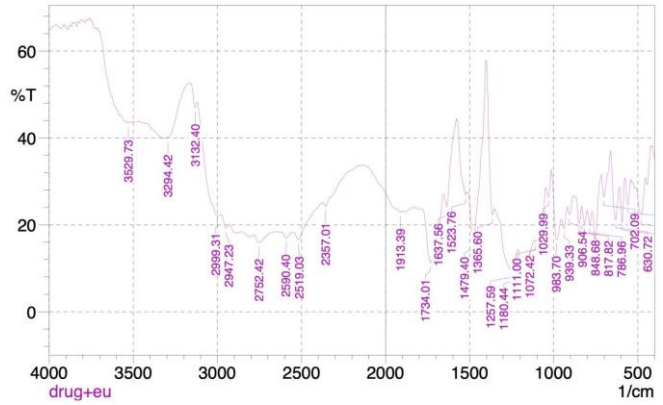

Fig. 4: FTIR spectra Of Drug Vonoprazan Fumarate + Eudragit L-100.

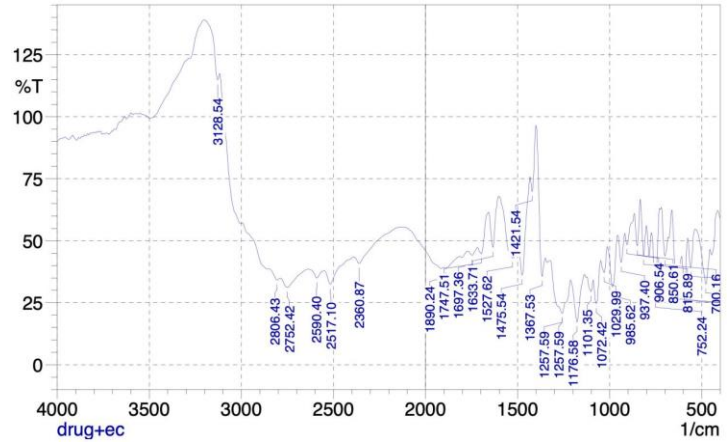

Fig. 5: FTIR Spectra of Drug Vonoprazan Fumarate + Ethyl Cellulose.

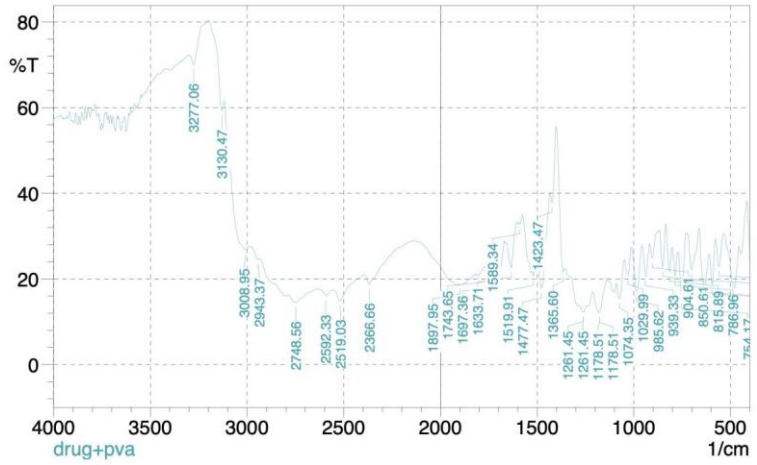

Fig. 6: FTIR Spectra of Drug Vonoprazan Fumarate + Polyvinyl Alcohol.

3.2 Evaluation of Vonoprazan fumarate loaded floating microsponges

3.2.1 Production yield: All of the MS formulations had production yields ranging from 64 to 86%. It was demonstrated that when the ratio of drug to polymer increased, so did the production yield.

Table 7: Production of formulated microsponges.

Sr. No.	Formulation Code	Production Yield (%)
1.	MS 1	64.2
2.	MS 2	63.9
3.	MS 3	66.3
4.	MS 4	68.2
5.	MS 5	74.5
6.	MS 6	79.4
7.	MS 7	78.9
8.	MS 8	77.7
9.	MS 9	86.6
10.	MS 10	78.2

3.2.2 Determination of Drug Content and Encapsulation Efficiency

Each sample's drug content was determined using the standard calibration curve. The effectiveness of encapsulation was unaffected by the different PVA concentrations (0.5 percent, 1.0 percent, and 1.5 percent) at the same amount of ethyl cellulose. Using the same amount of ethyl cellulose and 0.5, 1.0, and 1.5 percent of PVA, formulations demonstrated close entrapment efficiency ranging from 58 to 81%.

Table 8: Drug Content and Encapsulation Efficiency of Formulated Microsponges.

Sr. No.	Formulation Code	Drug Content (%)	Encapsulation Efficiency (%)
1.	MS 1	58.5	58.2
2.	MS 2	61.6	60.8
3.	MS 3	62.9	61.8
4.	MS 4	64.1	63.8
5.	MS 5	65.2	64.7
6.	MS 6	72.7	72.5
7.	MS 7	75.5	74.8
8.	MS 8	78.3	77.4
9.	MS 9	81.2	80.9
10.	MS 10	77.8	77.2

3.2.3 Analysis of morphology and surface topography of microsponges (SEM)

The scanning electron images of the selected formulation MS 9 were examined by SEM analysis operating at 5 kV and photographed at magnification ratio of 500x, 1500x, 2000x and 2500x. In scans captured by scanning electron microscopy, the selected formulation MS 9 displayed a spherical and uniform dispersion. Numerous pores were found on the microsponge surface by SEM analysis. When MS 9 was being made, the solvent diffused from the emulsion droplets, creating the many pores on the microsponge surface.

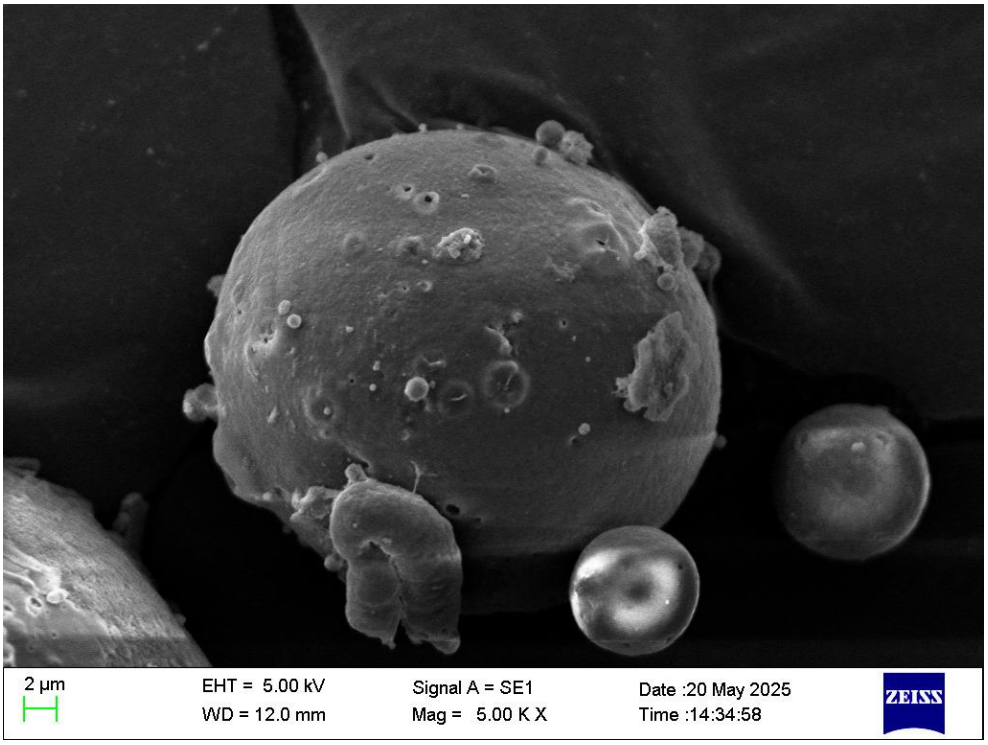

Fig. 7: SEM analysis of MS 9 Formulation.

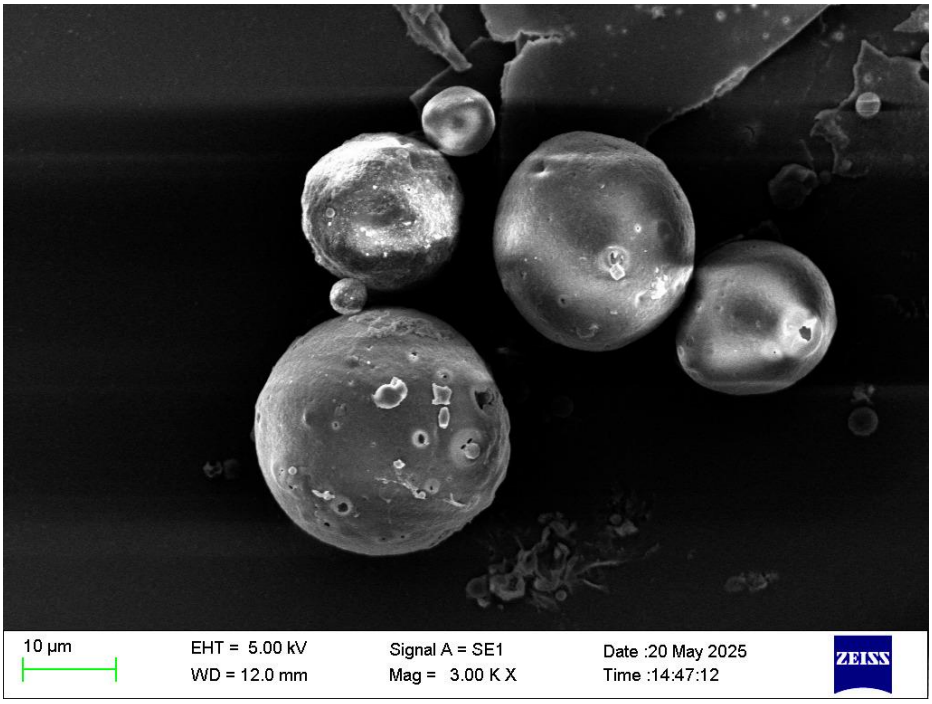

Fig. 8: SEM analysis of MS 9 Formulation.

3.2.4 Particle Size Analysis

The particle size analysis of MS 9 formulation was done. The average intensity distribution of microsponges was found to be 29,515 nm, i.e., 29.515 µm in size; whereas the average volume distribution of microsponges was found to be 34,611.2 nm, i.e., 34.6112 µm. As we know the average particle size of microsponges ranges from 5 to 300 µm therefore the particle size analysis results are positive.

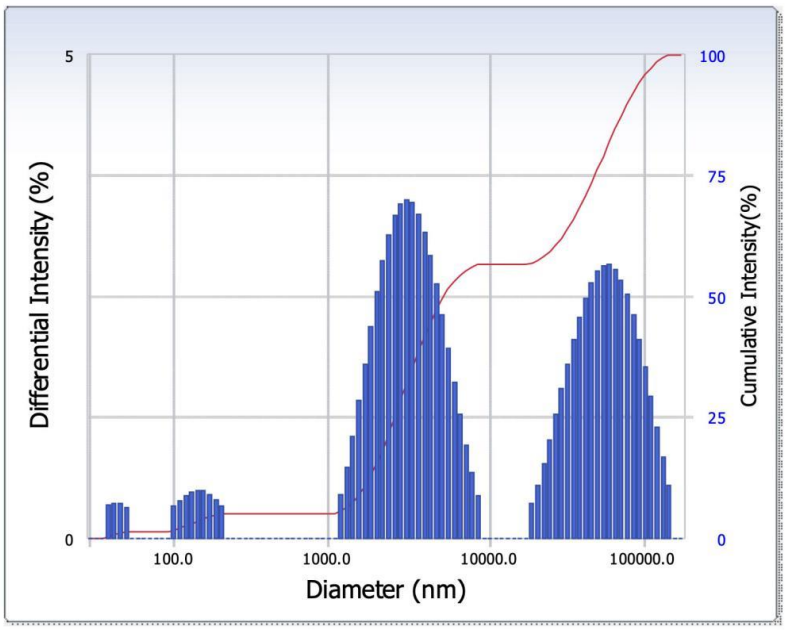

Fig. 9: Intensity Distribution Graph from Particle Size Analysis of MS 9 Formulation.

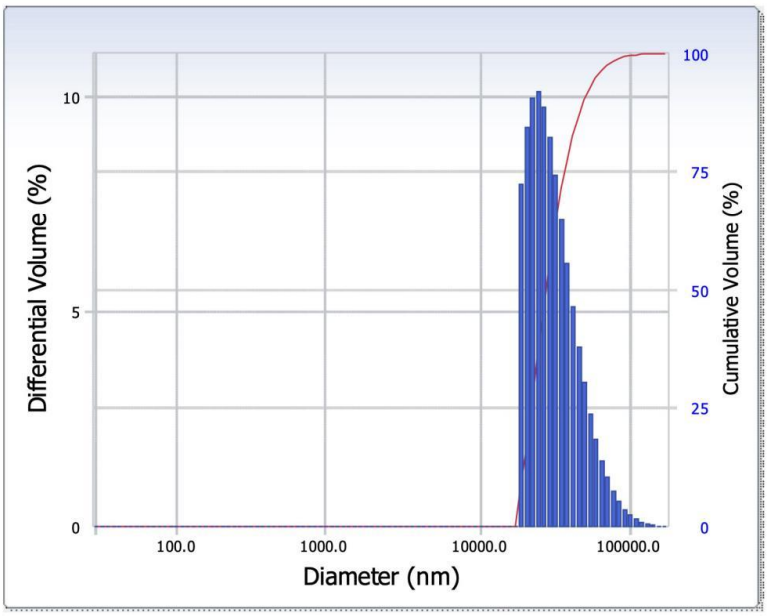

Fig. 10: Volume Distribution Graph from Particle Size Analysis of MS 9 Formulation.

3.2.5 Zeta Potential Analysis

The plot displays a peak at -19.38 mV, indicating that the charge of the microsponge particles was this level. The negative charges of the particles showed that there was no interparticle attraction.

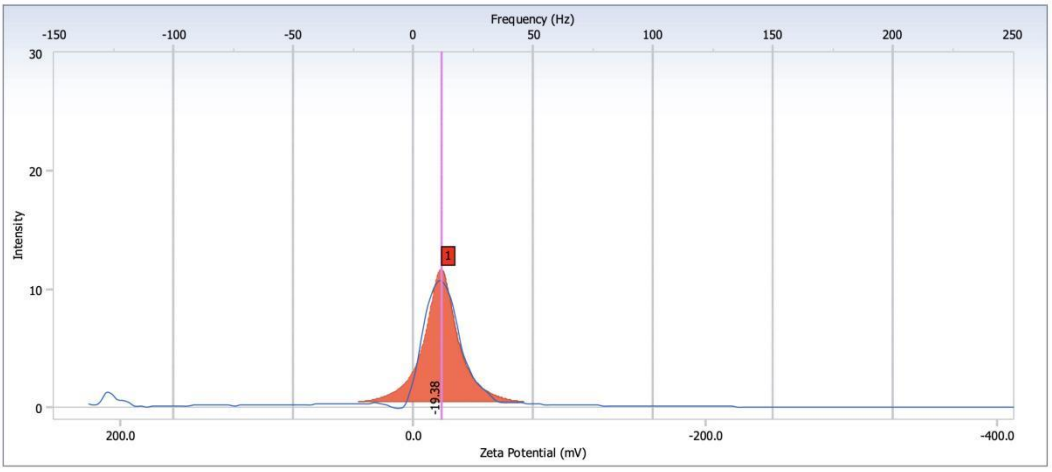

Fig. 11: Zeta Potential Analysis of MS 9 Formulation.

3.2.6 In vitro Drug Release Studies

The in vitro drug release studies was performed on MS 1 to MS 10 formulations by adding 900 mL of pH-1.2, 0.1N HCl to the vessel, the USP apparatus type II (Paddle Method) was put together. At a temperature of 37^{o}C ± 0.5 ^{o}C, the medium was allowed to equilibrate. The capsules were filled with prepared microsponges powder, put in the vessel, and spun at 50

rpm for 12 hours. 5 ml of the receptor fluid were taken out, filtered, and then reintroduced at predetermined intervals. Using the dilution media, the samples were diluted appropriately, and they were then examined spectrophotometrically at 230 nm.

Table 9: In vitro release profile of MS1 to MS10 Microsponges Formulations.

Sr. No.	Time (hrs)	% Drug Release									
		MS 1	MS 2	MS 3	MS 4	MS 5	MS 6	MS 7	MS 8	MS 9	MS 10
1.	0	0	0	0	0	0	0	0	0	0	0
2.	2	8.92	10.8	14.2	7.6	10.3	16.2	5.8	9.23	9.51	8.45
3.	4	27.2	25.91	28.6	19.2	28.4	26.8	22.35	22.89	20.45	14.63
4.	6	55.16	38.20	36.2	29.1	31.2	38.3	42.30	37.98	41.43	32.13
5.	8	63.44	50.12	48.50	37.5	43.3	47.2	50.87	52.34	54.22	48.74
6.	10	74.88	79.72	80.1	67.0	78.3	76.9	75.7	77.56	79.87	75.84
7.	12	82.68	82.25	82.45	80.20	81.7	84.12	83.52	84.81	84.93	80.23

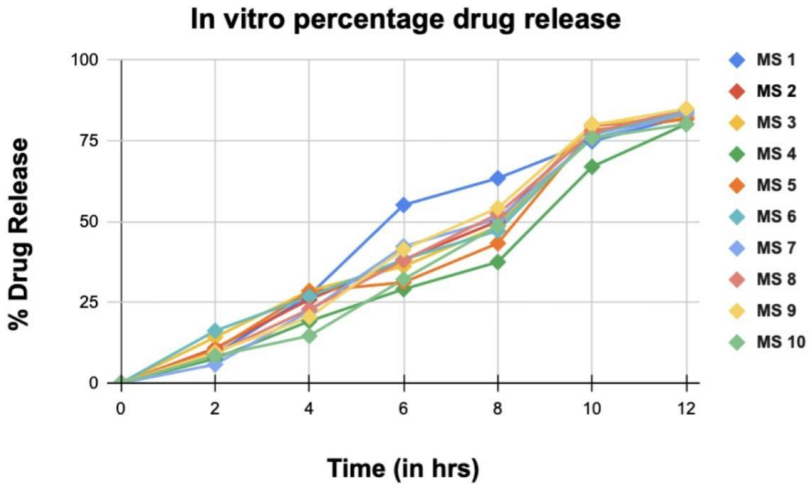

Fig. 12: % Drug Release Graph for MS 1 to MS 10 Microsponges Formulations.

3.2.7 Drug Release Kinetics

Table 10: Drug Release Kinetics of MS1 to MS10 Microsponges Formulations.

Sr. No.	Formulation Code	Zero order R^2	First Order R^2	Kors-Peppas R^2	Higuchi R^2	Hixson-Crowel R^2
1.	MS 1	0.948	0.992	0.958	0.948	0.988
2.	MS 2	0.969	0.91	0.99	0.949	0.935
3.	MS 3	0.952	0.885	0.974	0.92	0.91
4.	MS 4	0.958	0.881	0.986	0.909	0.912
5.	MS 5	0.932	0.868	0.957	0.896	0.892
6.	MS 6	0.962	0.894	0.97	0.922	0.921
7.	MS 7	0.986	0.949	0.977	0.979	0.971
8.	MS 8	0.987	0.934	0.997	0.966	0.96
9.	MS 9	0.981	0.938	0.991	0.965	0.961
10.	MS 10	0.968	0.923	0.974	0.935	0.943

3.2.8 In vitro Buoyancy Studies: The buoyancy of the microsponges is affected by particle size and density. The low density (0.4 g/cc) of EC in the formulations is linked to the in vitro buoyancy of microsponges. Compared to microsponges developed with a low EC concentration, those made with a high EC concentration floated higher. The microsponges generated with high PVA concentrations were less buoyant than those formed with low PVA concentrations.

Table 11: In vitro Buoyancy Studies of MS1 to MS10 Microsponges Formulations.

Sr. No.	Formulation Code	Buoyancy Studies (%)
1.	MS 1	62.3
2.	MS 2	65.9
3.	MS 3	70.1
4.	MS 4	52.4
5.	MS 5	71.2
6.	MS 6	74.2
7.	MS 7	65.8
8.	MS 8	72.2
9.	MS 9	77.5
10.	MS 10	68.6

3.2.9 Stability Studies: Formulation code MS9 was packed in capsule at room temperature (75% RH and 40 ^{o}C). At 30, 60 and 90 days, the capsules were assessed for assay and dissolution profile testing. Three parameters were taken into consideration for stability studies- Physical appearance, drug content and percentage cumulative percentage drug release.

Table 12: Accelerated Stability Studies of MS 9 Microsponges Formulation.

Sr. No.	Parameters	MS 9		
		30 Days	60 Days	90 Days
1.	Physical Appearance	Positive	Positive	Positive
2.	Drug Content	81.1	80.6	80.4
3.	% Drug Release	84.24	83.68	82.95

4. DISCUSSION

In preformulation studies of vonoprazan fumarate maximum wavelength of Vonoprazan fumarate was observed to be 229 nm which is found to be similar with reference standards. Calibration curve was obtained using different solvents and the R^2 value was found to be 0.9933 which is near 1 suggesting a strong linear relationship within the measured range. The melting point of the drug was found to be 203-204 ^{o}C which is similar to reference standard. The formulation of microsponges was done using quasi-emulsion solvent diffusion technique.

Eudragit L-100 was used as polymers which helped in extended release of the drug from the microsponges whereas ethyl cellulose was used as polymer for the buoyancy of the microsponges. The FTIR studies of drug with various polymers showed there was no incompatibility between the drug and the excipient. The evaluation of the microsponges was done on various parameters- the production yield ranged from 64 to 86% which demonstrated that when the ratio of drug to polymer increased, so did the production yield. The effectiveness of encapsulation was unaffected by the different PVA concentrations (0.5 percent, 1.0 percent, and 1.5 percent) at the same amount of ethyl cellulose. Using the same amount of ethyl cellulose and 0.5, 1.0, and 1.5 percent of PVA, formulations demonstrated close entrapment efficiency ranging from 58 to 81%. In scans captured by scanning electron microscopy, the selected formulation MS 9 displayed a spherical and uniform dispersion. Numerous pores were found on the microsponge surface by SEM analysis. When MS 9 was being made, the solvent diffused from the emulsion droplets, creating the many pores on the microsponge surface. The particle size analysis of MS 9 formulation was done. The average intensity distribution of microsponges was found to be 29,515 nm, i.e., 29.515 µm in size; whereas the average volume distribution of microsponges was found to be 34,611.2 nm, i.e., 34.6112 µm. As we know the average particle size of microsponges ranges from 5 to 300 µm therefore the particle size analysis results are positive. The plot displays a peak at -19.38 mV, indicating that the charge of the microsponge particles was this level. The negative charges of the particles showed that there was no inter-particle attraction. Drug release from vonoprazan fumarate microsponges was found to range from 80.20% to 84.93% from all formulations. From the results it was found that, as concentration of polymer increases, percentage of drug released decreases. The initial high drug release could be due to two reasons: first, the drug near or on the surface of the microsponges and second, well known porous nature of microsponges, the pores providing a channel for release of the drug. The microsponges differ from regular microspheres with their highly porous surface. This characteristic gives property to release the drug at a faster rate through the pores. The calculation of drug release kinetics of the percentage drug release showed that Korsmeyer-peppas model is the best fit model for the vonoprazan loaded microsponges. The buoyancy of the microsponges is affected by particle size and density. The buoyancy studies ranged from 62.3% to 77.5 %. Compared to microsponges developed with a low EC concentration, those made with a high EC concentration floated higher. The microsponges generated with high PVA concentrations were less buoyant than those formed with low PVA concentrations. Three parameters were taken into consideration for stability studies- Physical appearance, drug content and

percentage cumulative percentage drug release. Physical appearance reamined positive, drug content remained similar with an average of 0.35% degradation in drug content from 30 days to 90 days. Percentage cumulative drug release remained similar with an average of 0.645% degradation in percentage cumulative drug release from 30 to 90 days stability studies.

5. CONCLUSION

The ease of use, patient compliance, and formulation flexibility of drug delivery make it a popular delivery strategy. Floating systems significantly extend dose intervals, improve patient compliance, and lengthen the time that drugs are released. These methods enhance and prolong the window for absorption, and retain in the stomach. Initially employed for topical medication delivery, researchers now report that they are also used for oral and biopharmaceutical drug administration. Vonoprazan fumarate is a pyrrole derivative and reversible potassium-competitive acid blocker (P-CAB) with putative antacid effects. After administration, vonoprazan binds to the proton pump of the stomach hydrogen-potassium ATPase (H^+/K^+ ATPase) in a specific and competitive manner at or near its potassium ion (K^+) binding site, statically inhibiting K^+ binding. This reduces stomach acid levels by inhibiting the proton pump, preventing K^+ from activating the H^+/K^+ ATPase, and reducing gastric acid release. Microsponge technology uses polymeric microspheres with tiny, porous particles that contain an active component. This innovative drug delivery method has numerous benefits and is highly adaptable. The quasi-emulsion solvent diffusion technique proved effective for loading poorly soluble drugs into microsponges. Floating microsponges provide for regulated drug release and increased bioavailability of vonoprazan fumarate. This work introduces a novel way to treating stomach ulcers using microsponges' floating capacity.

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