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Advances in Bioresearch

ORIGINAL ARTICLE

Formulation and Evaluation of floating and swelling tablet of omeprazole: A comparison study done with natural and synthetic swelling agent

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ABSTRACT
The objective of this study was to formulate and evaluate floating and swelling tablet of omeprazole and check the effect of natural and synthetic swelling agent. Tablet are prepared by wet granulation method by using HPMC, sodium bicarbonate as polymer and effervescent agent and excipients. PVP k30 (5% in IPA) used as granulating agent. Floating properties of the tablet were determined by total floating time, floating lag time while swelling property of the tablet were determined by swelling index (water uptake studies) and in vitro drug and release. Tablets of all the batches had desired all above characteristics. It was concluded that upon increase in concentration of HPMC and swelling agent gives effective controlled and sustained drug release. From the comparison studies it was found that natural swelling agent were more effective.
Key words: *Floating and swelling tablet, Omeprazole, HPMC.*

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INTRODUCTION

The oral bioavailability of several drugs is limited by their unfavorable physiochemical characteristics or absorption in the precise part of the gastro-intestinal tract (GIT) [1]. Extended gastric retention improves both bioavailability and the solubility for drugs that are less soluble in a high pH environment and correspondingly reduce the drug waste by remain in the gastric waste [2]. Various approaches have been encourage the gastric retention of an oral dosage form in the stomach, including mucoadhesive/ bio-adhesive drug delivery system, swelling and expanding drug delivery system, high density system, floating drug delivery system [3].

The excellent floating system is effective only in the presence of sufficient fluid in the stomach. Otherwise buoyancy of the tablet may be hindered [4]. This limitation can be overcome by using a combination of a floating system with other gastro -retentive approaches such as high -density system, swelling system etc [5].

Omeprazole is in a class of drugs called proton pump inhibitors (PPIs) which block the production of acid by the stomach [6]. Proton pump inhibitors are used for the treatment of conditions such as stomach and duodenal ulcers, gastroesophageal reflux disease (GERD) and the Zollinger Ellison syndrome which all are caused by stomach acid [7]. Omeprazole inhibits the H (+)-K (-) ATPase in the proton pump of gastric parietal cells and highly effective inhibitor of gastric acid secretion [8]. It belongs to Biopharmaceutical Classification System (BCS) class II since it has low water solubility and high permeability [9]. Omeprazole having a half- life of 0.5 – 1 hr and a bioavailability of up to 30 -40% [10].

The objective of the present study was to formulate and evaluate floating and swelling tablet of omeprazole by using synthetic and natural swelling agent.

MATERIAL AND METHODS

Materials

Omeprazole was obtained from BLD pharma, Hyderabad, Telengana. India. HPMC K 100M, croscarmellose sodium, sodium bicarbonate, polyvinyl pyrrolidone K30, magnesium stearate, isopropyl alcohol, talc was received LOBA Chemicals, Pvt. Ltd. All the reagents and solvents used were of analytical grade.

Pre-formulation studies

The initial step in the rational development of an active pharmaceutical ingredient (API) and a drug product is pre-formulation testing. They have an effect on:

- Drug performance and development of an effective, stable, and safe dosage form.
- Selection of formulation components [11].
- The physicochemical properties of new drug substance [12].
- Drug excipient compatibility [13].

Drug characterization

Omeprazole was characterized by various tests of identification:

Organoleptic Properties:

The drug omeprazole was studied for organoleptic characteristics such as colour, odour, and appearance.

Determination of melting point

Melting point of omeprazole was determined by capillary method and DSC method was used to determine the melting point of Omeprazole. The point at which Omeprazole melts was recorded from thermometer and compared with literature value [14].

Solubility Profile

Solubility of omeprazole determined in organic solvent.

λ max selection

Stock solution (100 µg/ ml) of Omeprazole was prepared in0.1 N HCl. This solution was appropriately diluted with solvent to obtained suitable concentration. The UV – spectrum was recorded in range between 200 – 400 nm by using UV – visible double beam spectrophotometer. The wavelength of maximum absorption (λ max) was determined.

Construction of calibration curve [15]

Stock solution (100 µg / ml) of Omeprazole was prepared in 0.1 N HCl. This solution was appropriately diluted with solvent to obtained 0.2, 0.4, 0.6, 0.8, 1.0, 1.2 and 1.4 ppm concentration. The UV absorbance of solutions was recorded at 276 nm by using UV – visible double beam spectrophotometer.

Drug excipients compatibility study:

Fourier Transform Infrared Spectroscopy (FTIR) [16]

Compatability studies were done to recognize the possible interaction between drug Omeprazole and excipients utilized in the formulation. Physical mixture of drug and excipients in the proportion 1:1 were set up to study the compatibility. Drug polymer compatibility studies were completed utilizing FTIR spectroscopy. The IR spectra's were recorded in the middle of 500 – 4000cm.

Differential Scanning Calorimetry (DSC)

DSC is a thermo analytical technique in which difference in amount of heat required to increase the temperature of a sample and reference are measure as a function of temperature. Both the sample and reference mentioned at nearly sample temperature throughout the experiment.

Formulation and Evaluation studies

Preparation of floating and swelling tablet of Omeprazole:

Formulation of Omeprazole tablets are prepared by wet granulation method using hydrophilic polymer (HPMC K 100M), gas generating agent (sodium bicarbonate) and swelling agent (croscarmellose sodium). PVP K30 used as binder. The weight of drug in each tablet was maintained at 40mg. Total three formulation batches of tablet were prepared by changing amount of HPMC and croscarmellose sodium. The isopropyl alcohol was used as granulating agent. The powder mass was pass through sieve no. 60 and granulated using sufficient volume of isopropyl alcohol. The resulting dump mass was passed through sieve no. 14 and dried in oven. The resulting dried material was pass through sieve no. 16 and compressed using 16 station rotary press compression machine to obtained Omeprazole tablet.

Isolation of Fenugreek seed mucilage

The collected fenugreek seed was washed with distilled water to remove any adherent. The seed was grinded with small amount of water using mixer grinder to form slurry. The slurry thus prepared was precipitated with ethanol with continuous stirring with mechanical stirrer. The precipitate was then

washed with ethanol for 3 times and dried at hot air oven. The dried material was grinded using mixer grinder and pass through sieve no. 60. The powdered mucilage was used in further formulation.

Formulation of Omeprazole loaded floating and swelling tablet using Fenugreek mucilage

The Fenugreek seed mucilage was used as swelling agent in formulation of Omeprazole loaded floating and swelling tablet. The mucilage is polysaccharide extracted from various seeds. In present study, the mucilage was extracted from fenugreek seeds and utilized for formulation of Omeprazole tablet. The 25 mg of mucilage was we used in one tablet. It shown in Table 2 formulation of mucilage containing tablet of Omeprazole.

Table 1. Formulation Table Floating and Swelling Tablet of Omeprazole

Ingredients	Batch Code		
	F1	F2	F3
Omeprazole	40	40	40
HPMCK 100M	75	100	125
Sodium Bicarbonate	50	50	50
Croscarmellose sodium	20	25	30
PVP K30	20	20	20
Magnesium Stearate	5	5	5
Talc	2.5	2.5	2.5

All the tablet contain 5% w/v of isopropyl alcohol. From above formulation in which we had obtained F2 formulation as optimized formulation. On F2 formulation we had done comparison study between synthetic swelling agent and natural swelling agent.

Table 2. Formulation table of swelling and floating tablet of omeprazole with synthetic and natural swelling agent

Ingredients (mg/tablet)	Batch Code	
	F2	FM
Omeprazole	40	40
HPMCK 100M	100	100
Sodium Bicarbonate	50	50
Croscarmellose sodium	25	-
Fenugreek Mucilage	-	25
PVP K30	20	20
Magnesium Stereate	5	5
Talc	2.5	2.5

Evaluation Parameters

Pre-formulation Studies

A pre formulation study is an investigation into physical and chemical of the drug substance alone and when combine with excipients. Pre-formulation testing aims to provide formulator with knowledge that will help them create a stable, bioavailable dosage form that can be mass manufactured[14]. The parameters that were examined include angle of repose, bulk density, tapped density, carr's compressibility index and Hausner's ratio [17].

Angle of repose

The angle of repose (θ) for drug was determined by placing the granules in a funnel with the following critical dimensions: orifice diameter 10 mm and base diameter 65mm. The tip of the orifice of the funnel was at fixed height from the horizontal surface, and the granules were allowed to flow only under the force of gravity. It was calculated by equation,

$$\tan \theta = h / r$$

Where, h = height of the pile of granules

r = radius of base of cone

Tapped density

After carrying out the procedure as given in the measurement of bulk density, the cylinder containing granules was fixed on the tapped density apparatus. Measure the volume that is initial (poured) volume. Set the apparatus for approx.100 tapping. After tapping volume occupied by granules is noted final (tapped) volume. Then tapped density was calculated using the following formula.

Tapped density = mass of granules (gm)/ tapped volume of granules(ml)

Bulk density

Formulated granules of 10 g were introduced into a dry 50ml cylinder, without compacting. The level of granules was carefully marked without compacting and the unsettled apparent volume.Then bulk density was calculating using the following formula:

Bulk density = mass of granules (gm)/bulk volume of granules (ml)

Carr's compressibility index

From the above results, the compressibility of the granules was calculated as the following ratio.

Carr's Compressibility index (%) = (Tapped density – Bulk density / Tapped density) *100

Table 3. Relationship between Carr's index and Flow property

Sr. No	Compressibility Index (%)	Flow Character
1.	10	Excellent
2.	11–15	Good
3.	16–20	Fair
4.	21–25	Passable
5.	26–31	Poor
6.	32-37	Very poor
7.	>38	Very, very poor

Hausaner's ratio

The Hausner's ratio is defined as the ratio between tapped density and bulk density of granules.

Hausner's ratio = Tapped density / Bulk density

Table 4. Limits of Hausner's ratio values as per USP

Sr. No.	Hausner's Ratio	Flow Character
1.	1.00–1.11	Excellent
2.	1.12–1.18	Good
3.	1.19–1.25	Fair
4.	1.26–1.34	Passable
5.	1.35–1.45	Poor
6.	1.46–1.59	Very poor
7.	>1.60	Very, very poor

Evaluation of Tablet

Appearance

The tablet should be free from cracks, depressions, pinholes etc. The colour and the polish of the tablet should be uniform on whole surface. The surface of the tablets should be smooth.

Thickness and Diameter

The dimensions of the tablets are thickness and diameter. The tablets should have uniform thickness and diameter. Thickness and diameter of a tablet were measured using vernier calipers. It is expressed in mm.

Hardness Test

Monsanto hardness tester was used for the determination of hardness or tablet crushing strength of tablets

Friability

Friability of the tablets was determined using Roche's Friabilator. Pre-weighed sample of tablets was placed in the friabilator and operated for 100 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed. The tablets that loose less than 1% weight were considered to be compliant.

The % friability was calculated by using this formula:

% Friability = (1-W0 /W) × 100

Where, W0 is weight of the tablets before the test and W is the weight of the tablet after the test.

Weight Variation

Twenty tablets were selected randomly from the lot and average weight was determined. Then individual tablets were weighed and was compared with average weight.

Evaluation of Floating Behavior

Floating (Buoyancy) Lag Time (FLT)

The floating behaviour of the tablet was visually determined, according to the floating lag time. A tablet was placed in a glass beaker, containing 500ml of 0.1N HCl. The floating lag time is the time between tablet introduction and its buoyancy.

Total Floating Time

Duration of buoyancy is the time for which the tablet constantly floats on surface of the medium. The duration of buoyancy was measured by using a 500ml beaker containing 0.1N HCl.

Evaluation of Swelling Behavior

Swelling index (water uptake study)

The prepared tablets were placed in a glass containing 200 ml of 0.1 N HCl at 37 ± 0.5°C. The percentage of swelling at different time interval was calculated by the following equation.

SI (%) = (Wt -W0/Wt)*100

Where, SI is swelling index, Wt is weight of tablet at time t, wo is weight of the dry tablet before placing in the glass.

In vitro Drug Release [18]

In vitro dissolution of formulation was studied using the rotating paddle method (USP Type II apparatus). In this method, 900ml of 0.1 N HCl was used as a dissolution medium. The rate of stirring was 50 rpm. The tablet were placed in dissolution media maintained at 37+ 0.5^0C for a period of 12hours. A sample 5ml of the solution was withdrawn from the dissolution apparatus at the appropriate 1hr time intervals up to tablet remains float and swell completely and the sample were replaced with fresh 0.1 N HCl. The samples were filtered and absorbance of these solution was measured at 276nm using UV -visible double beam spectrophotometer.

Stability studies [18]

The studies designed to increase the rate of chemical degradation or physical change of a drug substance or drug product by using exaggerated storage conditions are known as accelerated stability studies. The formulated tablets were transferred in high density polyethylene container separately and stored at 25^0C/60% RH ± 5% RH for a period of 3 months as per ICH guidelines Q1A (R_2) stability testing of new drug substance and products. After completion of stated duration tablets were removed and evaluated for hardness, friability, weight variation, floating lag time, total floating time and swelling index.

RESULT AND DISCUSSION

Drug Characterization

Organoleptic Properties

The drug omeprazole was studied for organoleptic characteristics such as colour, odour, and appearance. The drug was evaluated for physical state, colour, odour was noted down.

Table 5. Description of drug

Test	Observed Result	Standard Result
Colour	White or almost white powder	White or almost white powder
Taste	Bitter	Bitter
Odour	Characteristic odour	Characteristic odour

Melting point determination:

Melting point of Omeprazole was determined by capillary method.

Table 6. Determination of Melting point

Sr. No.	Standard M.P. (^{0}C)	Observed M.P.(^{0}C)
1.	155 ^{0}C	156 ^{0}C

Solubility

Omeprazole is freely soluble in ethanol and methanol, and slightly soluble in acetone and isopropanol and very slightly soluble in water.

Determination of λ max

The UV spectrum of Omeprazole in 0.1N HCL has one maximum absorption band at 276 nm. Thus, 276 nm was used as wavelength maxima in further studies.

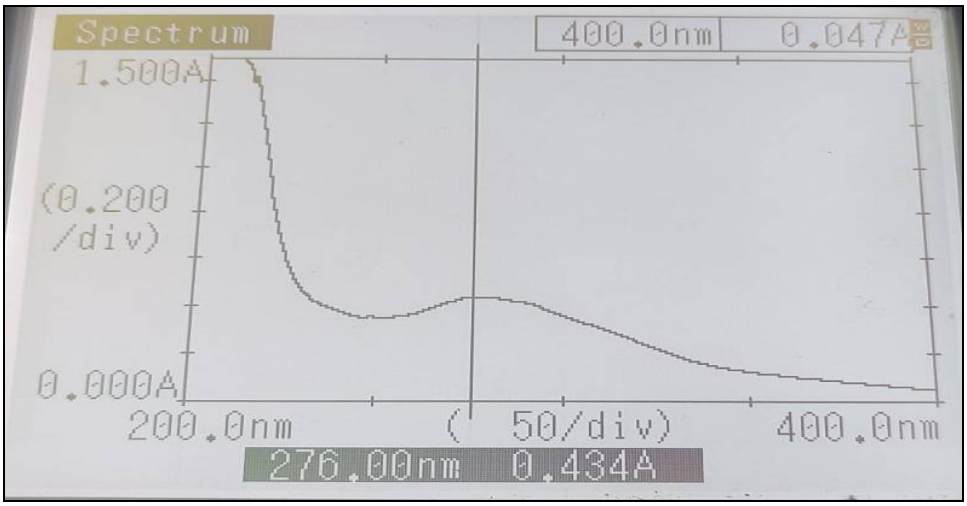

Figure 1. UV spectra of Omeprazole

Construction of calibration curve of omeprazole

The UV absorbance of solutions were recorded at 276 nm by using UV- Visible double beam spectrophotometer. Figure no.10 is the graphical representation of the calibration curve. The correlation coefficient value was found to be 0.9952. The value of correlation coefficient is close to one indicates good correlation between concentration and absorbance. The absorbance data of the standard solutions are shown in table.

Table 7. Calibration curve of Omeprazole in 0.1N HCl buffer

Sr. No.	Concentration in mcg/ml	Absorbance
1.	0. 2	0.139
2.	0.4	0.186
3.	0.6	0.262
4.	0.8	0.349
5.	1.0	0.447
6.	1.2	0.537
7.	1.4	0.619

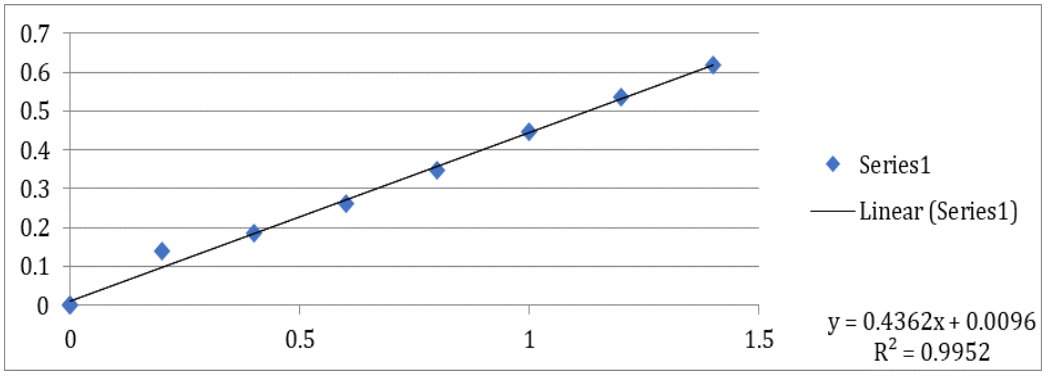

Figure no.2: Calibration curve of Omeprazole

Drug-Excipients Compatibility Studies

1 Fourier Transformed Infrared (FT-IR) Spectroscopic Analysis

The drug (API) and the Excipients used were subjected to FTIR checked for compatibility. The results were tested for incompatibility. One of the requirements for the selection of suitable excipients for the pharmaceutical formulation is its compatibility. The FTIR spectrum of drug and physical mixture were recorded to check the compatibility of the drug with excipients. FTIR spectrum omeprazole was identified which shows characteristics absorption of various functional group of omeprazole as shown in figure no.3.

The FTIR spectrum of omeprazole showed characteristic peaks at 3057.97which corresponds to - CH stretching. In addition to these peaks, the omeprazole also showed peak at 2949.57 cm^{-1} and 2903.93 cm^{-1} which corresponds to CH_3 stretching asymmetric and CH_3 stretching asymmetric respectively. The FTIR spectrum of omeprazole showed characteristic peaks at 1009.81 cm^{-1} which corresponds to S=O stretching. The compatibility of omeprazole with excipient was assessed by recording FTIR spectrums of physical mixture of drug and excipients. The FTIR spectrums of drug and drug: excipient mixture were recorded using FTIR spectrometer. FTIR spectrum of omeprazole and excipient mixture has represented in figure no.4. As highlighted in table no.9. The peaks of omeprazole were observed in physical mixture of omeprazole and excipient also at nearly same wave number which eventually indicated no or minimum interaction between drug and excipients.

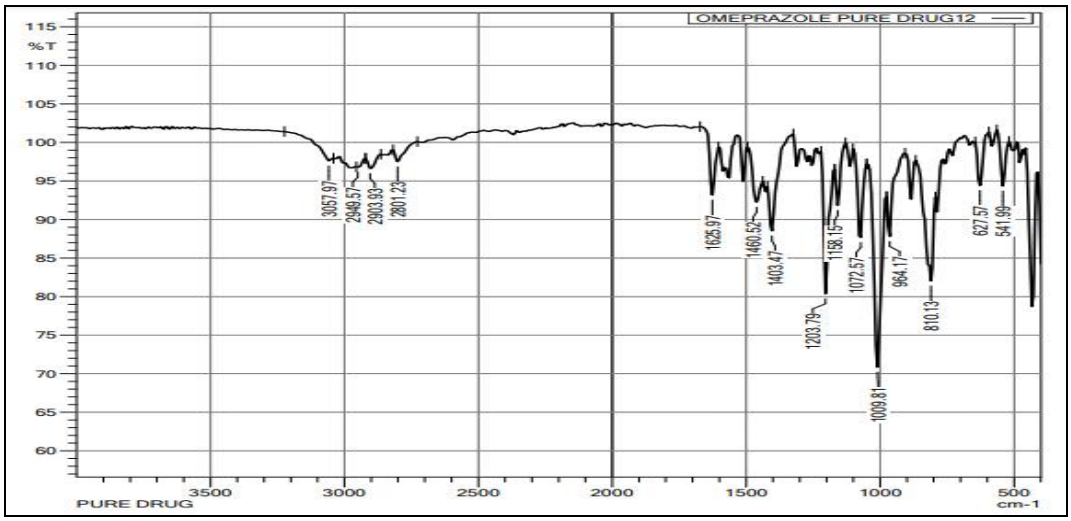

Figure no.3: FT-IR spectra of Pure Drug

Table no.8: FTIR interpretation of Pure Drug

Wavenumber	Assignation
3057.97	CH stretching
2949.57	CH_3 stretching asymmetric
2903.93	CH_3 stretching asymmetric
1625.97	CC stretching
1460.52	NH stretching
1009.81	S=O stretching
810.13	CH_3 rocking

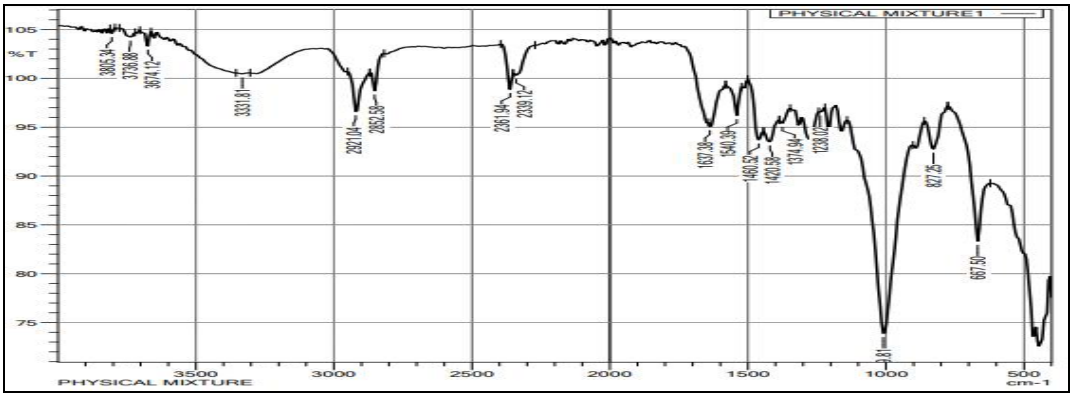

Figure no.4: FT-IR spectra of Physical Mixture

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Table no.9: FTIR interpretation of Physical Mixture

Sr. No	Functional Group	Observed IR Frequency of omeprazole (cm^{-1})	Observed IR Frequency of physical mixture (cm^{-1})
1	CH_3 stretching asymmetric	2949.57	2921.04
2	CH_3 stretching asymmetric	2903.93	2852.58
3	CC stretching	1625.97	1637.38
4	NH stretching	1460.52	1460.52
5	CH_3 rocking	810	827.25

Differential Scanning Calorimetry

DSC thermogram of drug is represented in figure no.5. The thermograms showed endotherm at 156.8^{0}C. Which corresponds to melting of omeprazole. The DSC analysis of pure drug and physical mixture revealed that there was negligible change in the melting point of Omeprazole when mixed with other excipients, indicating no modification or interaction between the drug and excipients.

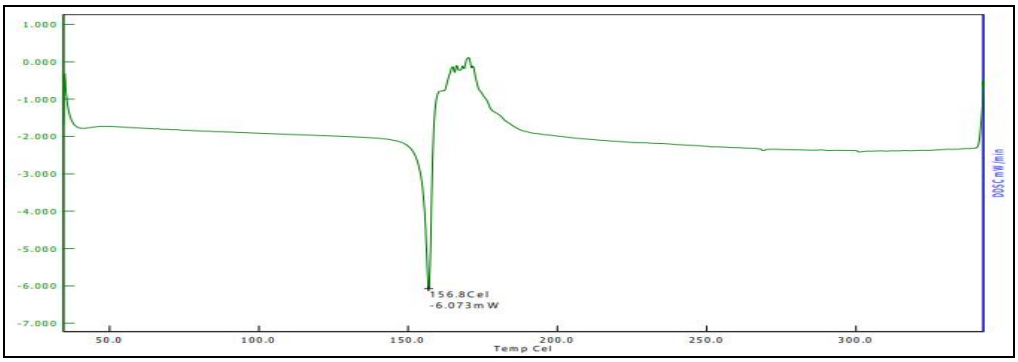

Figure no.5: DSC thermogram of Pure Drug

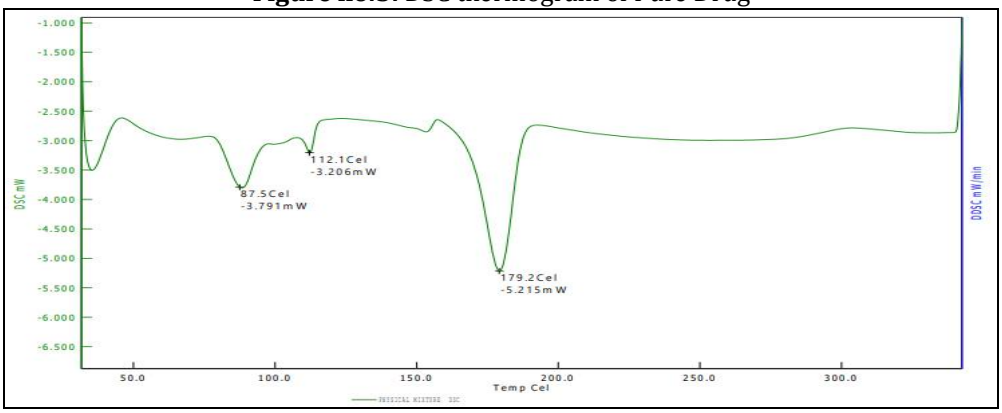

Figure no.6: DSC thermogram of Physical Mixture

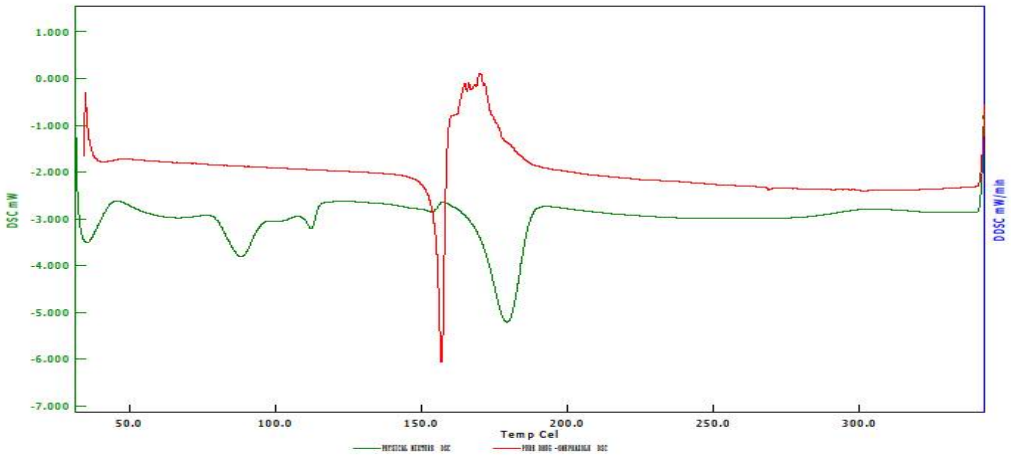

Figure no.7: Overlay of Pure drug and Physical mixture

Isolation of fenugreek seed mucilage

Mucilage was isolated from Fenugreek seeds by extraction, soaking and boiling with double distilled water and precipitating by addition of ethanol. The isolated mucilage was found to be brown in color as represented in figure no.9. The taste of mucilage was mucilaginous and dour was characteristics.

Figure no.8: Isolation of Fenugreek seed mucilage

Figure no.9: Mucilage of Fenugreek seed

Formulation Studies

Determination of granules characteristics:

The granules were evaluated for bulk density, tapped density, compressibility index and flow properties.

Table no.10: Determination of granules characteristics

Formulation Code	F1	F2	F3	FM
Bulk Density	0.52	0.49	0.55	0.55
Tapped Density	0.65	0.66	0.66	0.65
Angle of Repose	28.9	30.5	30.5	28.5
Carr's Index	16.4	16.9	16.9	15.5
Hausner's Ratio	1.03	1.23	1.23	1.02

The bulk density of granules value is used for determination of compressibility index and Hausner's ratio. Compressibility index of formulations F1, F2, F3 and FM values are 16.4%, 16.9%, 16.9% and 15.5% respectively indicate the flow property. Formulation F1, F2, F3 shows fair flow property while FM shows good flow property. Hausner's ratio of formulations F1, F2, F3 and FM values are 1.03%, 1.23%, 1.23%

and 1.02, respectively indicate the flow property. Formulation F1, FM shows excellent flow property, F2 and F3 shows fair flow property. Angle of repose of formulations F1, F2, F3 and F4 values are 28.9, 30.5,30.5and 28.5 respectively indicate the flow property.

EVALUATION OF TABLET

Appearance

Microscopic examination of tablets from each batch showed white, round shape, tablets plain on both sides.

Weight variation

The percentage weight variations of all formulations are shown in Table no.10.The tablets passed weight variation test as % weight variation was within pharmacopoeial limits of ±5% of the average weight.

Thickness

The thickness of all four formulations values obtained from 5.58 mm to 5.62 mm. The thickness of tablets are consumer acceptance and to maintain tablet to tablet uniformity. It's mostly related to tablet hardness.

Hardness

The hardness of formulations F1 value is 3.5 kg/cm2, F2 value is 3.5 kg/cm2, F3 value is 3 kg/cm2, FM value is 3.5 kg/cm2.The hardness of formulations F3 is lowest value compare to other formulations.

Friability

% friability values obtained in limits ensuring that the tablets were mechanically stable.

Drug content

The percentage drug content of the four batches were found to be between 97.43% to 99.90%, which is within acceptable limits indicating dose uniformity in each batch.

Table no.11: Evaluation of Prepared Tablets of Omeprazole

Parameters	**Formulation**			
	F1	F2	F3	FM
Weight Variation (gm)	10.2	10.7	10.42	10.81
Thickness (mm)	5.60	5.58	5.62	5.58
Hardness (kg/cm2)	3.5	3.5	3	3.5
Friability (%)	2.43	2.19	2.73	2.77
Drug Content (%)	94.87	97.30	96.85	98.37

EVALUATION OF FLOATING BEHAVIOUR

Sodium bicarbonate is formed within the tablet containing effervescent agent when it is brought in contact with acidic medium (0.1 N HCl). On immersion in 0.1 N HCl at 37 ^{0}C, the tablets floated and remained buoyant without disintegration. The results of floating lag time of all four formulations within 1 minute. Total floating time of F1 to F4 formulations are more than 8 hours.

Table no.12: Evaluation of Floating behaviour of Omeprazole tablet

Parameters	Formulation			
	F1	F2	F3	FM
Floating Lag Time or Buoyancy Lag Time (sec)	20.44	4.09	17.91	10
Total Floating Time (hrs)	More than 8	More than 8	More than 8	More than 8

EVALUATION OF SWELLING BEHAVIOUR

Swelling ratio describes the amount of water that is contained within the hydrogel at equilibrium and is a function of the network structure, hydrophilicity and ionization of the functional groups. Swelling study was performed on all the batches for 12 hours. The study showed that swelling of tablet increased up to 4-5 hours for all formulations but after that it decreased. The results of swelling index are given in Table no.13. The outermost layer of polymer hydrates, swells and a gel barrier is formed at the outer surface. As the gelatinous layer progressively dissolves and/or is dispersed, the hydration swelling release process is repeated towards new exposed surfaces, thus maintaining the integrity of the dosage form.

Table no.13: Evaluation of Swelling behaviour of Omeprazole tablet

Parameter	**Formulation**			
	F1	F2	F3	FM
Swelling Index (%)	78.56	85.16	82.54	89.04

***IN VITRO* DRUG RELEASE**

Cumulative % drug release

In-vitro drug release profile of tablets from each batch using USP dissolution apparatus Type II are shown in Table no.14. The plot of % cumulative drug released Vs. time (hr) was plotted for all formulations and depicted as shown in Figure no. 16. In the present study HPMC used was hydrophilic in nature, drug release involves (1) hydration and swelling of polymer and dissolution of active ingredients (2) transfer of the dissolved drug and soluble components into the bulk. The result of formulation F1 shows 85.07 % drug release, F2 shows 93.51 % drug release and F3 shows 81.10% drug release. All F1, F2 and F3 formulation contain synthetic swelling agent i.e. croscarmellose sodium and vary in concentration of HPMC K100 M. In that formulation shows F2 is better drug release compared with F1 and F3. In FM formulation contain natural swelling agent i.e. fenugreek mucilage and that compared with F2 formulation. In that FM formulation shows better drug release as compared with synthetic swelling agent.

Table no.14: Percent cumulative drug release from different formulation

Formulation code / Time (Hr.)	F1	F2	F3	Fenugreek Mucilage
1	21.66	20.58	15.98	29.38
2	29.23	25.43	20.80	35.09
3	39.00	29.77	27.01	42.33
4	40.57	39.55	29.60	50.96
5	54.61	47.08	36.26	57.33
6	60.05	54.51	39.03	66.71
7	67.15	59.01	42.36	72.36
8	79.43	65.55	48.41	78.71
9	83.65	74.58	54.09	85.50
10	89.52	82.02	60.88	89.08
11	90.41	90.99	73.39	94.43
12	85.07	93.51	81.10	96.15

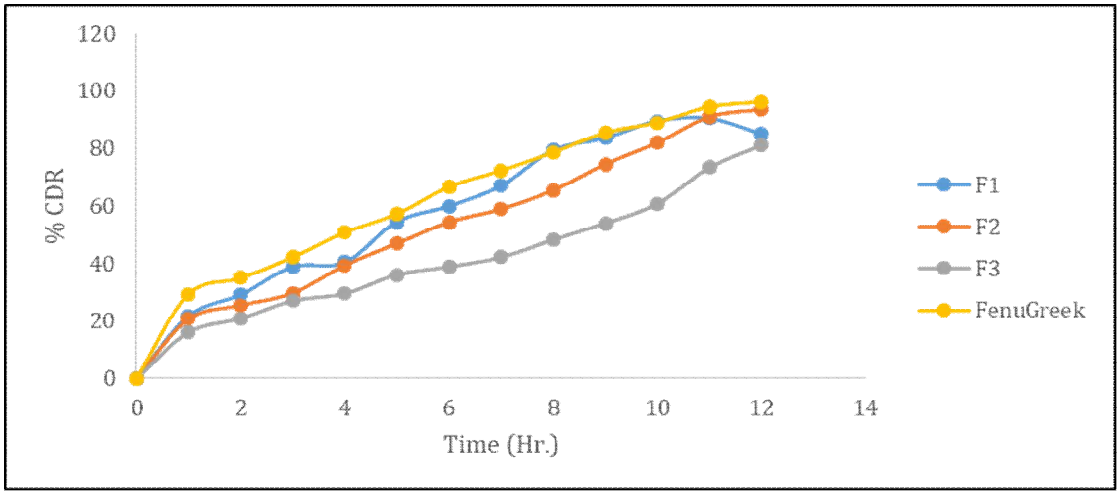

Figure no.10: Combine drug release profile of all batches

On basis of above evaluation parameters optimize formulation was found to be between F1, F2 and F3 is F2 which contain synthetic swelling agent i.e. croscarmellose sodium and comparative study was done between F2 and FM formulation. FM formulation contain natural swelling agent i.e. fenugreek mucilage. In that comparision study between natural and synthetic swelling agent contain optimum formulation was found to be FM. That FM formulation further carried out for stability study.

Selection of best formulation

From all above result formulation FM was selected as best formulation as it shows good flow properties of granules and there is shows better drug release as compared to other formulation prepared by synthetic swelling agent. Hence FM formulation selected as best (optimize) formulation.

Differential Scanning Calorimetry of Optimize formulation

There was a reduction in endothermic peak in physical mixture as compared to pure Omeprazole, suggesting that the interaction between the drug and excipients. It indicating that drug must stable with excipient.

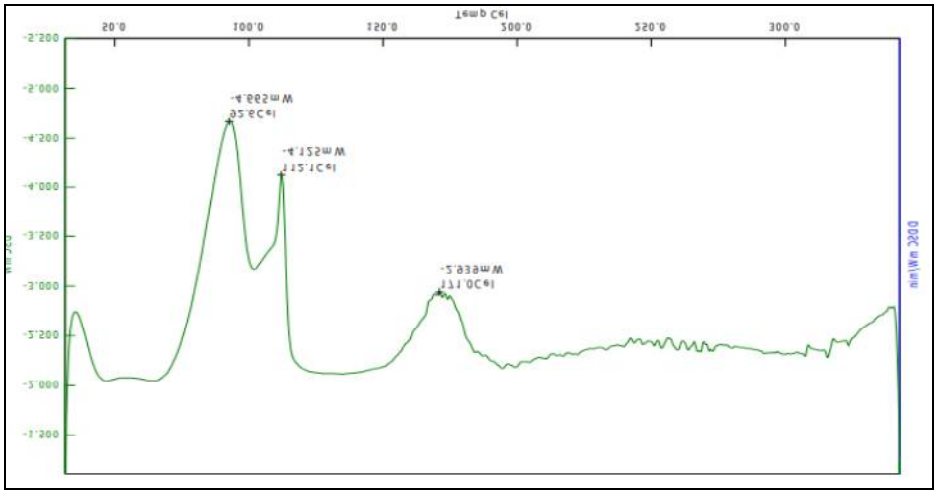

Figure no.11: DSC of FM formulation

Fourier Transformed Infrared (FT-IR) Spectroscopic Analysis of Optimize formulation:

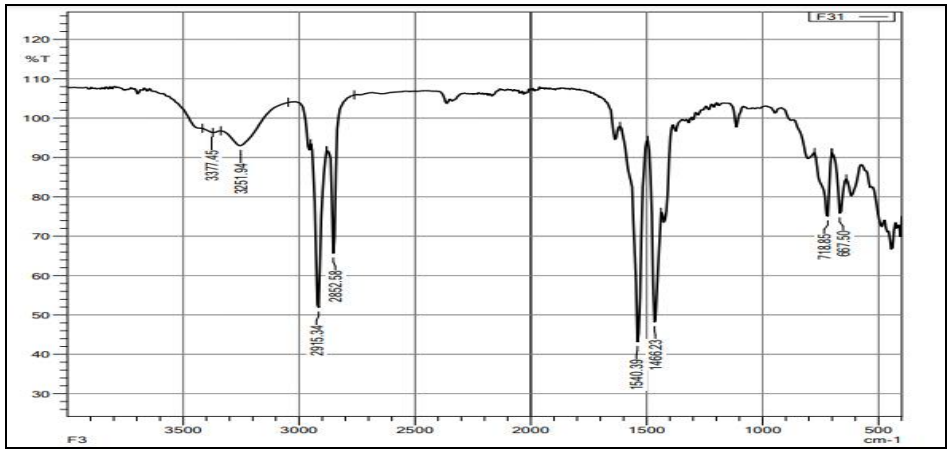

Figure no.12 FT-IR spectra of FM formulation

Table no.15: FT-IR interpretation of FM formulation

Sr. No	Functional Group	Optimum formulation IR (cm^{-1})
1	CH_3 stretching asymmetric	2921.04
2	CH_3 stretching asymmetric	2852.58
3	CC stretching	1637.38
4	NH stretching	1460.52
5	CH_3 rocking	827.25

Stability studies

The stability studies were carried out for optimised formulation FM. The optimized formulation FM was analysed for % CDR, drug content, floating lag time, total floating time, swelling index. There were no significant changes in % CDR, drug content, floating lag time, total floating time, swelling index of optimized formulation FM which indicates good stability during the 90 days stability studies.

Table no.16: Stability studies

Formulation FM	Floating lag time(sec)	Total floating time (Hrs)	Swelling index (%)	% CDR	Drug content
0 day	20.4	More than 8	77.50	85.07	94.87
30 day	4	More than 8	84.09	93.51	97.30
60 day	17.89	More than 8	81.41	81.10	96.85
90 day	10.12	More than 8	88.89	96.15	98.37

SUMMARY

Drugs with a limited absorption window could have their absorption phase extended by compounding them in a special pharmaceutical dose form with gastro retentive qualities. Following oral administration, this type of dosage form stays in the stomach and releases the medication over time in a regulated manner, ensuring that the medication is constantly given to the upper gastrointestinal tract's absorption sites. The goal of the current work was to develop omeprazole as both an expandable and floating drug delivery system in order to improve the drug's bioavailability and localise it at the absorption site. Omeprazole floating and swelling tablets were made with fenugreek mucilage acting as a natural swelling agent and sodium bicarbonate acting as a gas producing agent. HPMC, a hydrophilic polymer, and croscarmellose sodium were used as synthetic swelling agents. The wet granulation compression technique was used to prepared the tablets. The drug and polymer use were found to be compatible by FT-IR spectrum measurements. Evaluation criteria for these formulations included weight variation, thickness, hardness, friability, drug content, tablet density, floating test, swelling index, stability studies, and in-vitro release investigations. In the result and discussion section, all of these parameters' results are tabulated and visually shown. All four formulations met acceptable limits for the evaluation characteristics of tablet weight variation, thickness, friability, and drug content. Results from swelling studies and the floating test were satisfactory for all four formulations. All four formulations' medication releases were found to be satisfactory based on the results of an in-vitro release experiment conducted using the USP dissolving equipment Type II method. Stability studies showed for all four formulation to be stable at room temperature, no significant change was observed on following parameters such as % CDR, drug content, floating lag time, total floating time, swelling index.

CONCLUSION

Floating and swelling tablets of Omeprazole can be formulated with an approach to increase gastric residence and thereby improve drug bioavailability. An attempt to develop floating and swelling tablets of Omeprazole using sodium bicarbonate as gas generating agents HPMC as hydrophilic polymer, croscarmellose sodium as synthetic swelling agent and fenugreek mucilage as natural swelling agent by wet granulation compression technique was achieved. The formulated tablets showed compliance for various physiochemical parameters viz. tablet dimensions, total floating time, swelling index, in vitro drug release and drug content. The dissolution studies formulations of F1, F2, F3 were good release. In that three formulation contain synthetic swelling agent. Optimum formulation was found to be these three formulations was F2 because it shows excellent drug release as compare to other two formulation. In FM formulation contain natural swelling agent i.e. fenugreek mucilage. Comparison study was done between FM and F2 formulation which contain natural and synthetic swelling agent on basis of in vitro drug release. In that FM formulation show excellent drug release as compared with F2 formulation.

REFERENCES

1. Rathod, H.; Mehta, D.; Rathod, H. J.; Mehta, D. P.; Singh Yadav, J. (2016). A Review on Gastroretentive Drug Delivery Systems. Pharma Tutor; 4(7); 29-40
2. Shaik, T.; Sundaram, M. A.; Umasankar, K. (2014). Review On Gastroretentive Drug Delivery System; / International Journal of Research in Pharmaceutical and Nano Sciences. 3(3), 177 - 185.
3. Sowmya, B.; Arvapalli, S.; Gupta, A. V. S. S. S. (2019). A Review On Gastroretentive Drug Delivery System; WJPLS: 5[4]:101-110.
4. Pant, S. (2010). A Review On Gastroretentive Drug Delivery System. 5 (4), 2178–2187. IJPSR (2010), Vol. 1, Issue 6 . 1 (6), 7–18.
5. Mallikarjun, P. N.; Anusha, S.; Sai Nandini, V.; Rama Rao, B.; Kamala Kumari, P. V.; Srinivasa Rao, Y. (2021). Hydrogel: Responsive Structures for Drug Delivery. Int. J. Appl. Pharm. 13 (1), 65–76. https://doi.org/10.22159 /ijap.2021v13i1.39507.
6. Arora, S.; Ali, J.; Ahuja, A.; Khar, R. K.; Baboota, S. (2005). Floating Drug Delivery Systems: A Review. AAPS PharmSciTech. AAPS PharmSci . https://doi.org/10.1208/pt060347.
7. Hamedali, S. K.; Jayswal, M. G.; Shama, J.; Wasim, B.; Majaz, Q.; Khan, G. J. (2022). A Compressive Review On

Floating Drug Delivery System; WJPLS, Vol. 8, Issue 9, 174-179.
8. AN., M. (1997). Controlled and Novel Drug Delivery. ;; , CBS Publ. Distrib. 4th ed., 107-109.
9. Gandhi, L.; Akhtar, S. (2019). Comparative Study on Effect of Natural and Synthetic Superdisintegrants in the Formulation of Orodispersible Tablets. J. Drug Deliv. Ther. 9 (2), 507–513. https://doi.org/10.22270/jddt.v9i2.2404.
10. Salih, O. S.; Nief, R. A. A. (2016). Effect of Natural and Synthetic Polymers on the Properties of Candesartan Cilexetil Matrix Tablet Prepared by Dry Granulation. Asian J. Pharm. Clin. Res. 9, 161–170. https://doi.org/10.22159/ajpcr.2016.v9s3.14719.
11. Sherine, D.; Kumar, S. V. (2011). An Evolving Approach to Gastro Retentive Drug Delivery System. Int. J. Pharm. Res. Appl. 7, 2456–4494. https://doi.org/10.35629/7781-0706824832.
12. Kumar, A.; Srivastava, R. (2021). *In Vitro In Vivo* Studies On Floating Microspheres For Gastroretentive Drug Delivery System: A Review. 14, 2021. https://doi.org/10.22159/ajpcr.2021v14i1.39183.
13. Meka, L.; Kesavan, B.; Chinnala, K. M.; Vobalaboina, V.; Yamsani, M. R. (2008). Preparation of a Matrix Type Multiple-Unit Gastro Retentive Floating Drug Delivery System for Captopril Based on Gas Formation Technique: In Vitro Evaluation. AAPS PharmSciTech, 9 (2), 612–619. https://doi.org/10.1208/s12249-008-9090-4.
14. Sharma, B.; Khan, R. (2020). Formulation And Evaluaton Of Floating Tablet. World J. Pharm. Res. **2020**, 6. https://doi.org/10.20959/wjpr201713-9832.
15. Munawar, M. S.; Basha, S. A. A.; Imaduddin, M. (2014). Formulation and Evaluation of Bilayered Floating Tablets of Ondansetron and Capecitabine. Int. J. Pharm. Technol. 6 (2), 6764–6780.
16. Shep, S.; Dodiya, S.; Lahoti, S.; Mayee, R. (2011). Swelling System: A Novel Approach Towards Gastroretentive Drug Delivery System. Indo Glob. J. Pharm. Sci. 01 (03), 234–242. https://doi.org/10.35652/igjps.2011.23.
17. Kakar, S.; Batra, D.; Singh, R.; Nautiyal, U. (2013).Magnetic Microspheres as Magical Novel Drug Delivery System: A Review. J. Acute Dis. 2 (1), 1–12. https://doi.org/10.1016/s2221-6189(13)60087-6.
18. Kamalakkannan, V.; Puratchikody, A.; Prasanth, V. V.; Masilamani, K. (2011). Enhancement of Drugs Bioavailability by Floating Drug Delivery System - a Review. Int. J. Drug Deliv., 3 (4), 558–570.

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