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DESIGN AND CHARACTERIZATION OF GASTRO-RETENTIVE FLOATING TABLETS OF ALENDRONATE SODIUM

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Abstract

Objective: This study aimed to formulate and evaluate gastro-retentive floating tablets (GRDF) of alendronate sodium to enhance its oral bioavailability by prolonging gastric residence time and providing controlled drug release.

Methods: Combinations of hydroxypropyl methylcellulose (HPMC K4M), sodium carboxymethyl cellulose (Na CMC), and carbopol 934P as polymers, as well as sodium bicarbonate as a gas producing agent, GRDF tablets containing 50 mg alendronate sodium were made by direct compression. In vitro dissolution in simulated gastric fluid, buoyancy lag time and duration, swelling index, flow properties (angle of repose, bulk/tapped density, Carr's index, Hausner ratio), and physical parameters (thickness, hardness, friability, weight variation, and drug content) were assessed for the formulations (A1–A7). The compatibility of the medication and excipient was evaluated using FT IR and DSC analyses.

Results: The drug content (95.71–107.18%) and physical characteristics of all formulations were satisfactory. There was no discernible drug–polymer interaction, according to FT IR and DSC. The kind and concentration of the polymer affected the swelling index and floating ability; HPMC K4M considerably extended flotation and regulated drug release. Formulation A7 had the greatest swelling index (191%), longest floating duration (>12 hours), smallest floating lag time (48 seconds), and sustained drug release (~71% in 12 hours). Carbopol 934P had an impact on swelling and release rate, whereas the amount of sodium bicarbonate altered buoyancy lag time.

Conclusion: Optimised alendronate sodium GRDF tablets have good physicochemical properties, gastrointestinal retention, and drug release. HPMC K4M, Na CMC, and sodium bicarbonate increased floating and controlled release, indicating alendronate bioavailability might be improved.

Keywords: Gastro retention, alendronate sodium, Carbopol 934P,HPMC 4KM, Na-CMC, GRDF.

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Introduction

Osteoporosis is a disease of aging that leads to a gradual loss of bone strength and density [1]. Osteoporosis is diagnosed through both bone mineral density (BMD) measurement and conventional X-ray imaging [2-3]. Alendronic acid (Alendronate sodium) is a bisphosphonate drug used to treat both osteoporosis and other conditions affecting bone. Alendronate sodium is available as a single agent as well as in combination with vitamin D (2,800 IU and 5600 IU). Alendronate sodium is a bisphosphonate that inhibits osteoclast-mediated bone resorption and is available in its basic powdered form, which is white, crystalline, and nonhygroscopic; though essentially insoluble in chloroform, alendronate sodium is soluble in water and very slightly soluble in alcohol [4]. Alendronate inhibits bone resorption by osteoclasts and helps increase bone density [5]. The floating famotidine tablets are created and studied by Ravi Kumar et al. The floating tablets were prepared using gas-forming materials such as sodium bicarbonate, citric acid, hydroxypropyl methylcellulose (HPMC), and carbopol 934P [6]. The objective of this study is to prepare and evaluate gastro-retentive floating tablets of alendronate sodium with either the direct compress method or a polymer or combination of polymers.

Materials & Methods

Materials

Okasa Pharmaceuticals in Satara supplied the free sample of alendronate sodium, while S.D. Fine Chemicals, Mumbai furnished sodium CMC, and HPMC from Colorcon Asia Ltd, Goa. All other reagents and solvents used were analytical grade [7].

Methods

Direct Compression method was used in preparation of Alendronate sodium Tablet [8].

Preparation of a Floating Tablet

The floating tablet form, having 50 mg of alendronate sodium, was produced from a direct compression method. Alendronate sodium pure drug was mixed geometrically with the recorded amounts of lactose, sodium bicarbonate, carbopol 934P, sodium CMC, and HPMC K4M in a mortar and pestle for 10 minutes. The previously mentioned powder was then lubricated with magnesium stearate in a mortar and pestle for two minutes. Using a CLIT Pilot Press rotary tablet machine, the lubricated blend was compressed into tablets using a 12 mm flatface round tooling. The tablets produced were of appropriate hardness (6-9 kg/cm2), and a thickness of 4.0 mm as determined by the adjustment of compression.

Evaluation methods of Floating Drug delivery system

1. Fourier transform infrared analysis

The major uses of Fourier transform infrared spectroscopy are to identify organic, polymeric, and functional groups, along with certain inorganic compounds. The FT-IR readings of pure drug, polymer and drug-loaded formulations are not measured by this technique. Measurement is taken ordinarily at room temperature by scanning the spectra in the wave number range of 3600-400 cm-1 while the pellets are being prepared on a KBR press with a hydraulic pressure of 150 kg/cm2 [9].

2. Differential scanning calorimetry

Pharmaceutical water of hydration is characterized using DSC. Zinc standards are used to calibration the DSC temperature and enthalpy scale while thermograms of prepared preparations were obtained using a DSC machine with an intercooler. The sample preparations were placed in an aluminum pan and heated between 25 and 65 degrees Celsius at a controlled rate of 10 degrees Celsius per minute [9]

3. Evaluation of powder blend

a) Angle of repose

The angle of repose is the maximum angle between the surface of a powder pile and the horizontal surface. A lower angle of repose has better flow properties. The angle of repose can be determined by measuring the height (h) of the pile and the radius (r) of the base with a ruler.Tan θ = h/r 1

b) Bulk density

The bulk density of a material tells you its overall density. It consists of the true volume of inter-particle voids and intra-particle pore spaces of the powder. The packing of the powder particles is largely responsible for bulk. Bulk density is defined as follows: The bulk material density is calculated as the weight of the powder divided by its bulk volume.There may be a significant number of gaps between particles when they are densely packed. As a result, powder trapping enables the particles to migrate and eliminate voids to the lowest possible volume. The bulk volume is the volume that the powder occupies under these circumstances. Substituting this volume for a given weight of powder in equation (2) gives the bulk density [10].

c) Percentage porosity

The formula for total porosity is the same regardless of whether the powder is porous or not. Porosity provides information about hardness, disintegration, total porosity etc[10].

% porosity, € = void volume x100

Bulk volume

% porosity, € = *(bulk volumetrue volume)* x100

True density

4. Evaluation of floating tablets

a) Assessment of buoyancy performance of the FDDS:

The buoyancy performance is assessed via the weight data obtained. Simulated food and deionized water are used in two separate media. The results reflect enhanced buoyancy performance in higher molecular weight polymers demonstrated slower hydration rates, a greater effect was more clearly observed in simulated meal media than deionized water [11**]**.

b) Floating and dissolving performance in vitro:

The dissolve tests on a range of drugs are frequently carried out using USP dissolving equipmentUSP 28 states that "the dose unit is allowed to drop to the bottom of the vessel before the blade spins."Using a wire helix that is only a few turns long, the dose units that would typically float can be attached to a small, loose piece of nonreactive material. However, it has not been shown that standard USP or BP techniques can reliably predict the in vitro performance of floating dosage forms. Theophylline is only weakly soluble in water, and when Pillay et al. added a helical wire sinker to their swellable floating system, they discovered that the wire helix stopped the system from swelling and slowed down the drug's release. To overcome this limitation, the floating drug delivery device was fully submerged under a ring or mesh assembly, and the amount of drug released increased. Additionally, it was shown that the method was more reproducible and consistent. However, there was no appreciable change in the drug release when the recommended method was applied to a swellable floating system containing the highly water soluble drug diltiazem. Therefore, it was determined that unrestrained swelling, surface exposure,

and the medication's water solubility all influenced the release of the drug from swellable floating devices [11].

GRDDS is positioned similarly to other regular tablets, and the USP equipment with paddle is often used for the in vitro dissolving test. However, in certain cases, a considerably smaller paddle force operates on the floating dose form, which often floats on the top, because the vessel is huge and the paddles are at the bottom. Because floating dose forms don't rotate, they might not produce accurate or repeatable results. Similar issues arise with swellable dosage forms because the hydrogel may adhere to the paddle or vessel surface and provide unreproducible outcomes.

c) Weight variation

Composite tablet samples (representing 10 tablets each) are collected and weighed for each compression process. Then, there is an issue with the average result, even if the composite weight, divided by 10, yields an average weight. The United States Pharmacopeia (USP) establishes allowable weight variances for tablets as a percentage of the average weight of the sample to reduce this issue. The USP weight variation test is provided by weighing out 20 tablets separately and determining the average weight, and then comparing the weights for each tablet to the average weight. If no more than two tablets are outside of the % limit, and no tablets are outside of the % limit more than two times, the tablets are considered to have passed the USP weight variation test [11].

d) Hardness & friability:

Hardness is regulated as the "force required to break a tablet in thickness compression tests". Thus, hardness is also called tablet crushing strength. Among the instruments which are used to test hardness are the Monsanto, Pfizer, and sturdy Cobb testers. The laboratory friability tester is called the Roche Friabilator. Test method in this case includes a system which utilizes a plastic cylinder which revolves at 25 rpm to apply the cumulative effects of shock and abrasion to several tablets. For each revolution there is a drop of six inches of the tablet. The friabilator usually uses a previously weighed tablet sample of about 6 tablets and spins them 100 times. Ordinarily, conventional compressed tablets that lose less than about 0.5% to about 1.0% of their weight would be accepted. Most effervescent tablets have significant weight losses due to friability, which is when these tablets may require special stack packing [11].

5. Swelling systems

a) Swelling Index

Following the swelling dosage form's immersion in SGF at 370C, it is periodically withdrawn, and any dimensional changes-such as an increase in tablet thickness-are assessed/ diameter with time.

b) Water Uptake

It measures the swellable matrix's swelling property indirectly. Here, the dose form is taken out on a regular basis, and weight variations over time are calculated. So it is also termed as weight Gain.[10]

Water uptake = WU = (Wt – Wo) * 100 / Wo

Where, Wt = weight of dosage form at time t.

Wo = initial weight of dosage form.

Results

Evaluation of effervescent floating tablet formulations

IR spectrum of Alendronate Sodium

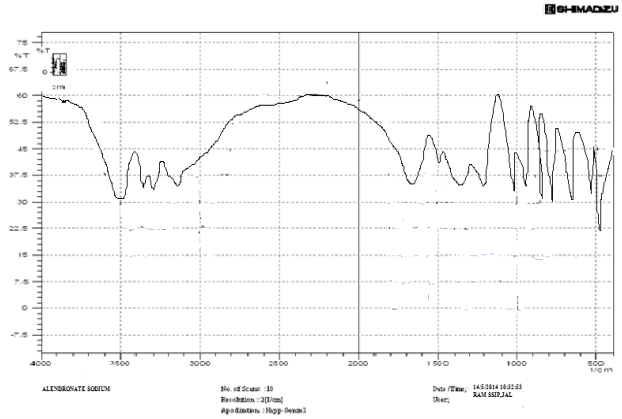

Fig 01: IR spectrum of Alendronate Sodium

IR spectra of mixture of Alendronate Sodium + HPMC K4M

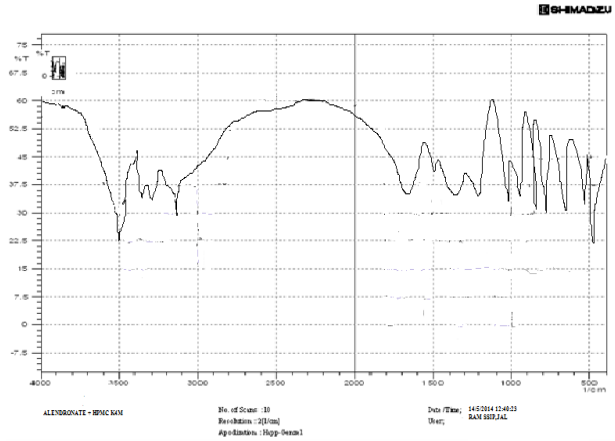

Fig 02: IR spectra of mixture of Alendronate Sodium + HPMC K4M

Infrared spectrum of Hydroxypropylmethyl cellulose K4M

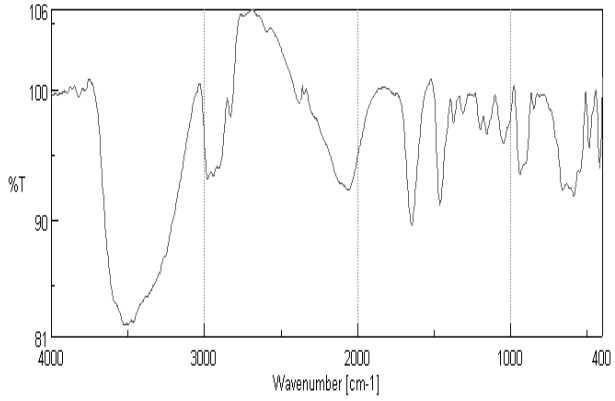

Fig 03: Infrared spectrum of Hydroxypropylmethyl cellulose K4M

Infrared spectrum of Carbopol 934

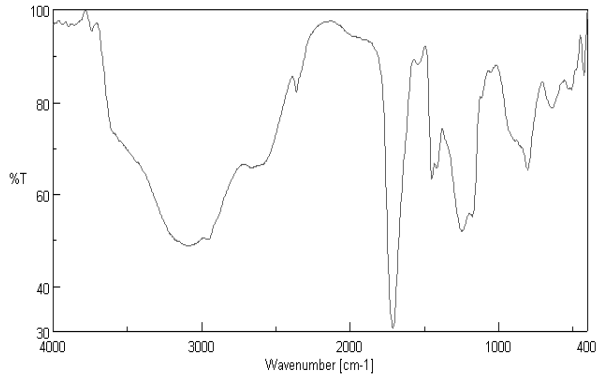

Fig 04: Infrared spectrum of Carbopol 934

FTIR spectrum of the CMC sample

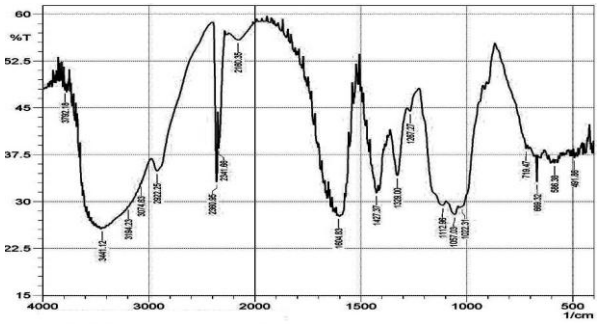

Fig 05: FTIR spectrum of the CMC sample

DSC thermograms (A) Alendronate Sodium (AS) (B) AS+HPMC K4M + sodium bicarbonate

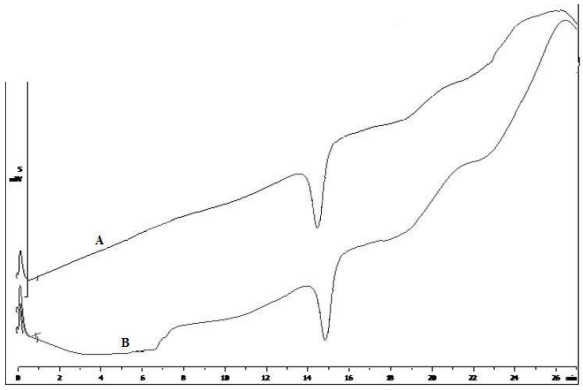

Fig 06: DSC thermograms (A) Alendronate Sodium (AS) (B) AS+HPMC K4M + sodium bicarbonate

DSC curve of the Na-CMC film from 50 to 250⁰C.

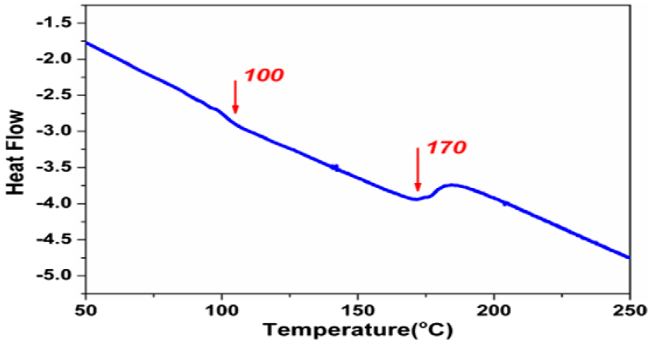

Fig 07: DSC curve of the Na-CMC film from 50 to 250⁰C.

Table 01 Result of study of physical parameters of Alendronate Sodium formulation A1-A7

Formulation	Angle of Repose (n=3)	Bulk Density (g/cm³) (n=3)	Tapped Density (g/cm³) (n=3)	Carr's Index (%)(n=3)	Hausner ratio H_R(n=3)
A1	29.2 ±0.62	0.583 ±0.006	0.734± 0.012	19.84±0.73	1.28± 0.05
A2	31.3 ±0.34	0.582 ±0.012	0.710± 0.007	23.08±0.6	1.18± 0.01
A3	30.5 ±0.17	0.541 ±0.012	0.711± 0.004	21.06±0.51	1.20± 0.01
A4	26.4 ±0.42	0.561 ±0.005	0.712± 0.030	23.05±0.43	1.21± 0.02
A5	28.2 ±0.33	0.610 ±0.070	0.743± 0.015	19.12±0.46	1.36± 0.01
A6	27.1 ±0.22	0.590 ±0.011	0.754± 0.060	19.22±0.56	1.30± 0.05
A7	25.4 ±0.55	0.570 ±0.014	0.720± 0.014	23.14±0.10	1.31± 0.01

Table 02: Composition of Floating tablets of Alendronate Sodium

Ingredient	A1	A2	A3	A4	A5	A6	A7
Alendronate Sodium	50	50	50	50	50	50	50
HPMC K4M	95	100	105	100	100	95	90
Sodium CMC	28	30	32	–	28	30	30
Carbopol 934P	45	40	35	25	30	20	15
Lactose	116	115	110	149	106	109	108
Sodium Bicarbonate	52	58	62	70	76	82	86
Magnesium Stearate	6	6	6	6	6	6	6
Total	400	400	400	400	400	400	400

Table 03: Physicochemical properties of Alendronate Sodium floating tablets

Batch Code	Average Weight (mg)	Thickness (mm)	Diameter (mm)	Hardness (kg/cm^2)	Friability (%)	Drug Content (%)
A1	398	4.12 ± 0.05	12.10 ± 0.04	7.6 ± 0.03	0.70 ± 0.06	101.24 ± 0.18
A2	403	4.00 ± 0.03	12.05 ± 0.03	8.2 ± 0.05	0.74 ± 0.05	98.87 ± 0.17
A3	392	4.03 ± 0.06	12.03 ± 0.06	9.1 ± 0.04	0.81 ± 0.02	103.45 ± 0.19
A4	402	4.15 ± 0.03	12.07 ± 0.05	7.3 ± 0.02	0.92 ± 0.05	105.39 ± 0.15
A5	408	4.10 ± 0.04	12.05 ± 0.03	7.7 ± 0.03	0.68 ± 0.03	106.52 ± 0.11
A6	393	4.06 ± 0.03	12.02 ± 0.07	8.5 ± 0.05	0.72 ± 0.04	107.18 ± 0.16
A7	406	4.19 ± 0.05	12.01 ± 0.06	7.5 ± 0.04	0.79 ± 0.05	95.71 ± 0.13

Table 04: Dissolution drug release data of batch A1 to A7

All values are expressed as mean ± SD, n=3, A1-A7=code of formulations

Time (min)	A1	A2	A3	A4	A5	A6	A7
0	0	0	0	0	0	0	0
30	6.012	9.874	12.987	14.658	18.832	12.654	13.545
60	8.214	11.982	16.21	20.464	28.725	17.274	17.083
120	10.947	15.742	18.753	25.328	33.119	20.964	19.379
180	14.895	19.908	23.982	34.514	39.547	24.768	24.496
240	18.284	23.215	27.661	38.093	42.868	30.886	28.648
300	21.693	26.792	31.484	41.264	49.927	36.637	32.508
360	26.378	31.103	35.739	44.835	53.682	42.15	36.695
420	30.126	35.497	38.302	48.204	57.395	49.738	39.264
480	33.804	38.749	42.536	51.372	60.428	54.946	43.492
540	39.502	44.179	48.933	58.284	63.395	60.201	50.026
600	45.187	49.661	51.247	60.769	65.944	66.583	52.447
660	48.715	53.284	55.693	65.376	68.821	71.852	57.104
720	53.216	57.838	61.285	69.875	71.436	77.129	62.934

Table 05: swelling index of batch A1 to A7

Time (min)	A1	A2	A3	A4	A5	A6	A7
0	0	0	0	0	0	0	0
15	37.42	36.89	38.23	31.46	39.88	36.14	30.82
30	52.17	50.85	47.56	34.39	50.33	39.23	52.68
60	65.36	70.24	62.87	53.48	67.92	66.34	70.76
120	82.24	82.76	82.93	74.15	86.31	83.47	99.46
180	100.12	99.78	103.84	89.06	117.34	105.28	120.06
240	113.87	116.23	126.05	99.24	121.66	123.13	139.78
300	119.23	124.68	129.47	106.32	132.44	131.22	154.02
360	132.08	134.09	135.86	113.42	148.06	138.57	157.89
420	136.24	139.87	141.56	120.04	151.39	141.48	172.11
480	143.18	144.32	148.42	118.15	157.54	147.83	175.28
540	151.06	151.18	155.21	113.05	168.27	152.89	177.85
600	148.62	147.42	148.23	103.76	167.24	150.96	179.43
660	145.35	145.84	148.07	102.42	163.78	149.24	182.76
720	135.16	135.82	137.63	100.56	157.53	138.76	191.03

Table 06: Floating ability of various Alendronate Sodium tablet formulations

Batch Code	Floating Lag Time	Floating Duration (min)	Integrity
A1	Did not float	Did not float	Remained intact
A2	Did not float	Did not float	Maintained structure
A3	32 min	20	Remained intact
A4	28 min	40	Disintegrated after 6 hrs
A5	22 min	64	No structural changes

A6	41 min	>720	Physically stable
A7	48 sec	>725	Maintained integrity

All values are expressed as mean ± SD, n=3, A1-A7= Formulation codes.

Discussion

Alendronate sodium showed a melting point of 273-2770C. The melting point was between 274 to 2780 degrees Celsius. A Shimazdu 1800 spectrophotometer (broadband UV-visible) was used to scan the absorption maxima of the standard solution in the wavelength range of 400–800 nm. The value of the absorption maxima was found to be 525 nm. All of the significant peaks of alendronate sodium are present in the infrared spectrum. The infrared spectrum illustrated that the major peak and some characteristic peaks was for the measure functional group. (Fig 01). Alendronate sodium and the physical mixture of polymers (HPMC K4M) indicated via infrared spectra that they did not show interaction. All of the significant peaks of both the drug and polymer were observed in the spectrum. As a result it can be concluded that no major changes occurred to the physical characteristics of the alendronate sodium and HPMC K4M. The DSC thermogram of alendronate sodium, is an endothermic peak at 2720C, and HPMC K4M is a melting endothermic at 34.400C, Table No. 1 shows the summary of the studies performed on physical parameter for Alendronate Sodium formulation A1–A7 and Table 02 shows the formulation of Alendronate Sodium floating tablets.The dimensions of the tablets from each of the formulation A1 to A7 was evaluated by measuring the diameter and thickness with a vernier caliper respectively. The diameter and thickness ranged from 3.98 ±0.02 to 4.22 ±0.07. The hardness ranged from 7.2±0.03 to 9.0±0.02kg/cm 2 using a Monsanto hardness tester. Table 03 shows the drug content release ranged from 96.33±0.12 to 107.48±0.0. After seven hours, the drug release percentage for all formulations A1–A7 was 50%. As indicated in Table 04, the medication release after 12 hours was 79.40%. Time was taken into consideration while calculating the swelling index. The swelling index rose with time because the weight gain from the tablet grew in proportion to the rate of hydration. Later, it steadily declined as the tablet's exterior gelled layer dissolved into the dissolving solvent.The rate of release may be influenced by the kind of polymer, the concentration of the polymer that is causing erosion, drug diffusion, and swelling. While taking these absorption characteristics into consideration, the purpose of the study was to systematically explore the effect of formulation variables on the release and floating properties of the Alendronate Sodium drug delivery system. The hypothesis is that if a formulation containing Alendronate Sodium has a long gastric residence time and is also floating in the stomach for one extended period of time, the oral bioavailability would also have increased.

The polymers used in floating drug delivery systems should be very swellable in the least amount of time. Therefore, HPMC was chosen as the primary swellable polymer. In addition to HPMC, HPMC K4M (high viscosity polymer) was used, so the floating capability could be prolonged. Additionally, an increase in viscosity of a polymer delays the drug dispersion from the dosage form. Carboxypolymethylene or Carbopol 934P was added to the dose form to prolong retention in the stomach and prevent gastric emptying. Carbapol was incorporated into the formulation in order to adhere the dosage form onto the inner wall of the stomach, and potentially limit the release of alendronate sodium from the dosage form. This principle of adhesive dosage forms works with the polymer class of polymers which is made up of both swelled and adhesive properties. Batch A7 developed the longest floating time in the 7 series formulation when averages are considered in comparison to A6, A5, A4, A3, A2, and A1.

The total floating time can be attributed to the amount of HPMC. The gas produced by NaHCO3 was produced safely due to the thick gel that was formed due to the polymer in the formulation which aided in the floating time. The thick gel which was obtained by the viscosity created and polymer content ability aided in the expansion of the gas produced by NaHCO3, and duration of floatation in trials on the 7 series dosage forms The value in relation to floating lag time demonstrated that floating lag time had decreased with the amount of gas producing agent used. The findings are supported by Park et al., findings, which include that floating lag times decrease and floating capacity increased with greater usage of gas producing agent (NaHCO3).Due to its adhesive characteristics, carbopol acted not only as a swelling agent but in addition aided in gastric retention. However, the flotational characteristics were also influenced by carbopol. The tablets were subjected to physicochemical tests, which involved initial characterization of hardness, thickness, percentage weight variation, friability and drug content. The tested parameters for all formulations fell into appropriate ranges. The sequence of swelling in these polymers may demonstrate the rates at which the preparations will absorb liquid and swell as highlighted in a study of water uptake. All of the polymer swelling and maximum liquid uptake occurred in the first 10 hours, after which erosion resulted in a gradual decrease in swelling.

Conclusion

In the realm of gastric retention, we have seen that achievi ng true gastric retention requires overcoming numerous c hallenges.But we are closer than ever to witnessing a mor e significant shift in gastric retention devices from the res earch and development stage to the production and mark et stage.In some cases, extending a delivery system's stom ach residence duration is preferable in order to improve t he drug's therapeutic efficacy substance.

Examples of such medications are furosemide, levodopa, s otalol HCL, and ciprofloxacin.Medicines with site-specific absorption can have the bioavailability improved by employing GRDD systems to control the gastrointestinal transit of oral dose forms. GRDFs have an additional benefit if the drug is predominately absorbed in the upper GIT (e.g., stomach, duodenum, and jejunum). There are many GRDD methodologies being investigated that have their own advantages and disadvantages. It is reasonable to expect GRDD systems to be more widely accepted in the future as a means of systemic drug delivery and to increase the effectiveness of multiple types of pharmacotherapy. The currently available polymer-based, non-effervescent and effervescent FDDS products appear to provide a very beneficial advantage in modifying controlled oral dosing for drugs based on stomach retention and buoyancy advantages. In designing a floating dosage form, the first and foremost requirement is that the formulation's density must be lower than that of stomach fluid. It is relatively safe to state that these types of dosage forms will afford the most beneficial outcomes for the treatment of GIT-related diseases and for extended effects on a medication with a short half-life.In recent years, different drugs have been developed as floating drug delivery systems, which restrict the area of drug release to the stomach and provide continuous release of the drug. The buoyant preparation approach is a simple and practical way to improve the duration of stomach residence time for the dose form, as well as the duration over which the drug is released. The polymer mediated buoyancy approach to floating drug delivery is an example of applying the principles of buoyancy and delayed gastric emptying, which is, at least to date, a very successful example of controlling the oral delivery of drugs. The major prerequisite for developing a floating drug delivery system is that the density of the dose form needs to be less than that of gastric fluid. Thus, floating drug delivery systems are typically best intended for treatment of conditions localized to the gastrointestinal tract as well as to get long acting drugs with a short half-life.The floating tablets of Alendronate sodium were prepared and evaluated in terms of a number of physicochemical properties including content uniformity, weight variation, thickness, hardness, and friability, and satisfactory results were obtained. The two excipients, HPMC K4M and sodium bicarbonate, impacted different properties of the Alendronate sodium floating tablets. Overall floating time and drug release were predominantly impacted by HPMC K4M in the formulation, while sodium bicarbonate impacted the buoyancy lag time. In addition, Carbopol 934P was noted to influence drug release.The study clearly shows that by lengthening the gastrointestinal residence time, a promising controlled release floating tablet of alendronate sodium may be created, hence enhancing its bioavailability. Every formulation was confirmed to be stable under the tested conditions and storage time. To determine the necessary dosage and prove the effectiveness of these compositions, further thorough research is needed.

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Conflicts of Interests

There are no conflicts of interest.

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Authors Contributions

All the authors have contributed equally.

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