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Design and Invitro Evaluation of Montelukast Sodium Effervescent Floating Tablets

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Abstract: *Asthma is a chronic respiratory disorder requiring frequent dosing of drugs due to their short half-life, which leads to poor patient compliance. Montelukast Sodium is a potent leukotriene receptor antagonist used in asthma management but it has a short half-life of 2.7 to 5.5 hours and a narrow absorption window in the upper gastrointestinal tract. To overcome these limitations and to reduce dosing frequency, the present research work was carried out to design and evaluate gastroretentive effervescent floating tablets of Montelukast Sodium for sustained drug release.*

The floating tablets were prepared by direct compression method using xanthan gum as natural release retardant polymer, sodium bicarbonate as gas generating agent, and citric acid as acidifying agent to maintain buoyancy. Lactose was used as diluent, while talc and magnesium stearate were incorporated as glidant and lubricant respectively. A total of nine formulations F1-F9 were prepared by varying the concentration of xanthan gum from 20 mg to 60 mg per tablet. All the formulated tablets were subjected to evaluation of physicochemical parameters like hardness, friability, weight variation, drug content, floating lag time, total floating time, and in-vitro drug release study in 0.1N HCl.

Among all nine formulations, F3 containing 40 mg xanthan gum was selected as the optimized formulation. It exhibited minimum floating lag time of 39.06 ± 0.03 sec, total floating time of more than 12 hours, and maximum cumulative drug release of 99.8 ± 0.14% in 12 hours. The optimized formulation showed good physicochemical properties with hardness of 4.5 ± 0.10 kg/cm², friability of 0.54%, and drug content of 99.6 ± 0.12%. The FT-IR study confirmed the absence of any chemical interaction between Montelukast Sodium and the excipients used..

Keywords: Montelukast Sodium, Gastroretentive, Floating tablets, Xanthan gum, Zero order kinetics, In-vitro evaluation

I. INTRODUCTION

The present research work was aimed to design and evaluate gastroretentive effervescent floating tablets of Montelukast Sodium for in vitro studies, to increase the gastric residence time and achieve sustained drug release for improved therapeutic efficacy in asthma. The tablets were designed using xanthan gum as release retardant polymer, sodium bicarbonate as gas generating agent and citric acid as acidifying agent. The designed tablets were evaluated for various physicochemical parameters, floating behavior and in-vitro drug release study.

Montelukast Sodium is a leukotriene receptor antagonist (LTRA) used in the prophylaxis and chronic treatment of asthma. It has a short biological half-life of 2.7–5.5 hours and is administered as oral tablets once daily at a dose of 10 mg. However, conventional tablets have short gastric residence time, leading to incomplete drug release. Hence, in the present investigation, effervescent floating tablets of Montelukast Sodium were designed to reduce frequency of dosing, achieve maximum gastric residence time and to improve drug availability.

Gastroretentive drug delivery systems have gained significant importance in recent years because they help retain the drug in the stomach for a longer duration. This is particularly useful for drugs that are absorbed mainly in the upper part of the gastrointestinal tract. Among these systems, floating drug delivery is a promising approach, as it allows the dosage form to remain buoyant in gastric fluids and release the drug in a controlled manner.

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Montelukast Sodium is a commonly used anti-asthmatic drug that works as a leukotriene receptor antagonist. However, its short biological half-life and the need for sustained action can reduce patient compliance. Therefore, designing a sustained release formulation that can prolong the drug's residence time in the stomach is beneficial for improving its therapeutic efficiency.

Effervescent floating tablets are specially designed using gas-generating agents that produce carbon dioxide when they come in contact with gastric fluid. This gas gets trapped within the tablet matrix, allowing it to float on the stomach contents. Such systems not only enhance gastric retention but also provide controlled drug release, ultimately improving bioavailability and reducing dosing frequency.

The success of a floating drug delivery system largely depends on the selection of suitable polymers. Xanthan gum plays an important role in controlling the drug release and maintaining the integrity of the tablet. It swells in the presence of gastric fluid and forms a gel-like structure that helps in sustained drug release. For a tablet to float, its density must be lower than that of gastric fluid. This is achieved by incorporating effervescent agents like sodium bicarbonate that generate gas, reducing the overall density of the system.

Evaluation of tablet properties is essential to ensure the quality and performance of the formulation. Parameters such as hardness, friability, weight variation, and drug content help determine the mechanical strength and uniformity of the tablets. In vitro studies are widely used to assess the performance of floating tablets before in vivo testing. These studies include buoyancy tests, swelling behavior, and drug release profiles.

Overall, the development of floating drug delivery systems offers several advantages in pharmaceutical formulations. It enhances drug stability, improves patient compliance, and provides controlled drug release over an extended period. Such systems are especially beneficial for drugs like Montelukast Sodium, where prolonged action is desired.

II. REVIEW OF LITERATURE

Gastroretentive drug delivery systems have been extensively studied to improve bioavailability of drugs with narrow absorption window. Among various approaches, floating drug delivery system has gained significant attention.

1. Studies on Montelukast Sodium

Singh et al. (2018) developed floating tablets of Montelukast Sodium using HPMC K4M and reported 94% drug release in 10 hours with floating lag time of 45 sec. The study concluded that sustained release formulation improves patient compliance in asthma.

Patel et al. (2020) formulated effervescent floating tablets of Montelukast Sodium and observed that sodium bicarbonate 50mg was sufficient to provide buoyancy for more than 12 hours.

2. Studies on Xanthan Gum as Release Retardant

Talukdar et al. (2017) investigated xanthan gum as a release retardant polymer for floating tablets of Atenolol. The study revealed that xanthan gum forms a strong gel matrix upon contact with gastric fluid which effectively controls drug release. Formulation with 40mg xanthan gum showed 98.2% release in 12 hours with zero order kinetics.

Kumar et al. (2019) reported that xanthan gum at 30-50mg concentration provides optimum floating lag time of 30-50 sec and total floating time >12 hours. The polymer concentration directly affects the swelling and drug release behavior.

Sharma et al. (2021) compared xanthan gum with other natural polymers and concluded that xanthan gum provides better control over drug release due to its high viscosity and pH independent swelling property.

3. Studies on Effervescent Floating System

Rosa et al. (2016) developed floating tablets using sodium bicarbonate and citric acid as gas generating agents. The study confirmed that 1:0.5 ratio of sodium bicarbonate to citric acid provides rapid gas generation and minimum floating lag time.

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4. Rationale for Present Study

From the literature survey, it is evident that Montelukast Sodium has short half-life and requires frequent dosing. Xanthan gum has shown promising results as release retardant for floating tablets. Hence, the present study was designed to develop effervescent floating tablets of Montelukast Sodium using xanthan gum to achieve sustained release for 12 hours.

III. AIM AND OBJECTIVES

Aim

To design and evaluate gastroretentive effervescent floating tablets of Montelukast Sodium using xanthan gum as release retardant polymer for sustained drug release up to 12 hours.

Objectives

1. To carry out literature survey on Montelukast Sodium, xanthan gum and gastroretentive floating drug delivery systems.
2. To carry out preformulation study and drug-excipient compatibility study by FT-IR spectroscopy.
3. To formulate nine batches F1-F9 of effervescent floating tablets of Montelukast Sodium by direct compression method using different concentrations of xanthan gum.
4. To evaluate the prepared tablets for physicochemical parameters like hardness, friability, weight variation, drug content, floating lag time and total floating time.
5. To perform in-vitro dissolution study of all formulations in 0.1N HCl for 12 hours.
6. To determine the release kinetics of optimized formulation using Zero order, First order, Higuchi and Korsmeyer-Peppas models.
7. To select the optimized formulation based on minimum floating lag time, maximum total floating time and desired drug release profile.

IV. PLAN OF WORK

The present work was planned in the following manner:

1. Literature Survey:

Collection of literature related to gastroretentive floating drug delivery systems, Montelukast Sodium, and xanthan gum from various journals, books, and internet sources.

2. Procurement of Drug and Excipients:

Montelukast Sodium was obtained as a gift sample. Xanthan gum, sodium bicarbonate, citric acid, and other excipients were procured from laboratory chemical suppliers.

3. Preformulation Study:

Drug-excipient compatibility study by FT-IR spectroscopy.

4. Preparation of Tablets:

Preparation of nine formulations F1-F9 of effervescent floating tablets of Montelukast Sodium by direct compression method using different concentrations of xanthan gum.

5. Evaluation of Tablets:

Evaluation of pre-compression parameters and post-compression parameters like hardness, friability, weight variation, drug content, floating lag time, and total floating time.

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6. In-vitro Dissolution Study:
In-vitro drug release study of all formulations in 0.1N HCl for 12 hours using USP Type II dissolution apparatus.

7. Release Kinetics Study:
Application of drug release data to various kinetic models like Zero order, First order, Higuchi, and Korsmeyer-Peppas to determine the mechanism of drug release.

8. Result Compilation:
Compilation of results, graphical representation, and statistical analysis.

9. Conclusion:
Writing conclusion based on the results obtained.

V. DRUG PROFILE

1. Name: Montelukast Sodium
2. Category: Leukotriene receptor antagonist, Anti-asthmatic
3. Chemical Name: [R-(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropaneacetic acid, monosodium salt
4. Molecular Formula: C35H35ClNNaO3S
5. Molecular Weight: 608.18 g/mol
6. Description: White to off-white hygroscopic powder
7. Solubility: Freely soluble in ethanol, methanol, and water; practically insoluble in acetonitrile
8. Melting Point: 135-137°C
9. Half-life: 2.7 to 5.5 hours
10. Bioavailability: 63% to 73%
11. Dose: 10 mg once daily for adults
12. Mechanism of Action: It selectively antagonizes leukotriene D4 at the cysteinyl leukotriene receptor, CysLT1, in the human airway. This prevents airway edema, smooth muscle contraction, and inflammation.
13. Pharmacokinetics: Rapidly absorbed after oral administration. Peak plasma concentration achieved in 3-4 hours. Extensively metabolized in liver.
14. Adverse Effects: Headache, abdominal pain, dyspepsia, cough
15. Uses: Prophylaxis and chronic treatment of asthma, relief of symptoms of seasonal allergic rhinitis
16. Why Suitable for GRDDS: Short half-life, narrow absorption window in upper GIT, and need for sustained action make it an ideal candidate for gastroretentive floating tablets.

VI. MATERIALS AND METHODS

Materials
The following materials were used in the present study. Montelukast Sodium was obtained as a gift sample. Xanthan gum, Sodium bicarbonate, Citric acid, Lactose, Talc, and Magnesium stearate were of analytical grade and procured from Loba Chemie, Mumbai.

Table: List of Materials Used

Sr.No	Material	Category	Supplier
1.	Montelukast Sodium	Drug	Gift Sample
2.	Xanthan Gum	Release retardant	Loba Chemie
3.	Sodium Bicarbonate	Gas generating agent	Loba Chemie
4.	Citric Acid	Acidifying agent	Loba Chemie

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5.	Lactose	Diluent	Loba Chemie
6.	Talc	Glidant	Loba Chemie
7.	Magnesium Stearate	Lubricant	Loba Chemie

Methodology

1 Preformulation Study

Drug-excipient compatibility study was carried out by FT-IR spectroscopy. The spectra of pure drug and physical mixture of drug with excipients were recorded.

2 Preparation of Effervescent Floating Tablets

Nine formulations F1-F9 were prepared by direct compression method. All the ingredients were weighed accurately and passed through sieve no. 60. Montelukast Sodium, xanthan gum, sodium bicarbonate, citric acid, and lactose were mixed in geometric dilution. Talc and magnesium stearate were added and mixed for 5 min. The final blend was compressed into tablets using 8 mm flat-faced punch on a single punch tablet machine.

Table: Composition of Floating Tablets F1-F9 (mg/tab)

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Monteluakst sodium	10	10	10	10	10	10	10	10	10
Xanthan Gum	20	25	30	35	40	45	50	55	60
Sodium Bicarbonate	50	50	50	50	50	50	50	50	50
Citric acid	25	25	25	25	25	25	25	25	25
Lactose	90	85	80	75	70	65	60	55	50
Talc	3	3	3	3	3	3	3	3	3
Magnesium stearate	2	2	2	2	2	2	2	2	2
Total weight	200	200	200	200	200	200	200	200	200

Experimental Work

1. Preparation of effervescent floating tablets of montelukast sodium

The present research work involves the formulation of nine batches of effervescent floating tablets F1-F9 containing Montelukast Sodium as model drug. The primary aim was to investigate the effect of different concentrations of xanthan gum on floating behavior and sustained drug release. *The detailed quantitative composition of all formulations is shown in Table 2 under section 7.2.2.* In all batches, the concentration of Montelukast Sodium 10mg, Sodium bicarbonate 50mg as gas generating agent, Citric acid 25mg as acid source, Talc 3mg as glidant, and Magnesium stearate 2mg as lubricant was kept constant. Xanthan gum concentration was varied from 20mg to 60mg and lactose was used as diluent to adjust the total tablet weight to 200mg.

Direct compression method was adopted for preparation of tablets due to moisture sensitivity of Montelukast Sodium and hygroscopic nature of effervescent components. Wet granulation technique was deliberately avoided because exposure to water during granulation may cause premature effervescent reaction between sodium bicarbonate and citric acid, resulting in loss of floating ability. Moreover, heating during drying step may cause degradation of Montelukast Sodium. Direct compression method is simple, economical, and avoids stability issues associated with moisture, making it most suitable for effervescent floating formulations.

The manufacturing process was performed under controlled humidity conditions below 40% RH to prevent absorption of moisture by the powder blend. All ingredients were accurately weighed on calibrated digital balance as per the formula given in Table 2. Individual ingredients were passed through sieve no. 60 separately to break any lumps and achieve uniform particle size, which is critical for uniform mixing and consistent tablet weight. The sifted drug and excipients except talc and magnesium stearate were mixed thoroughly in a polybag using geometric dilution technique for 10 minutes. Geometric mixing was employed because of the low drug content 10mg per 200mg tablet to ensure content uniformity in the final dosage form.

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After obtaining a uniform dry mix, talc and magnesium stearate previously sifted through sieve no. 60 were added to the blend. The lubrication process was carried out for 5 minutes only to avoid over-lubrication, which can lead to decrease in tablet hardness and delay in disintegration. The lubricated blend was evaluated for pre-compression parameters like angle of repose, bulk density, and Carr's index to confirm suitable flow property for compression. The blend exhibiting good flow was then compressed into tablets using 8mm flat-faced circular punches and die set on a single punch tablet compression machine.

During compression, the machine parameters were optimized to produce tablets of uniform weight 200 ± 5mg and hardness 4-6 kg/cm². This hardness range was selected specifically for floating tablets because very hard tablets show delayed penetration of gastric fluid and hence delayed floating, while soft tablets may disintegrate prematurely in the stomach. The compressed tablets were dedusted and checked for physical defects like capping, lamination, or chipping. The finished tablets were immediately packed in airtight glass containers containing silica gel sachets as desiccant to protect from atmospheric moisture and stored at room temperature until subjected to post-compression evaluation studies.

VII. EVALUATION OF EFFERVESCENT FLOATING TABLETS

The prepared effervescent floating tablets F1-F9 were subjected to various pre-compression and post-compression evaluation parameters to assess their quality and performance characteristics.

A. Pre-compression Evaluation of Powder Blend

The powder blend of all formulations F1-F9 was evaluated for following flow properties before compression to ensure suitability for direct compression:

1. Angle of Repose

It was determined by fixed funnel method. The powder was allowed to flow through a funnel fixed at a height of 2 cm from the base. The height and radius of the powder pile was measured and angle of repose was calculated using formula: $\tan \theta = h/r$. The values were found in the range of 24.2° to 28.6°, indicating good flow property.

2. Bulk Density and Tapped Density

A known quantity of powder was poured into a graduated measuring cylinder and initial volume V_0 was noted for bulk density. The cylinder was then tapped 100 times and final volume Vf was noted for tapped density. Values were calculated using formula: Bulk density = M/V_0, Tapped density = M/Vf.

3. Carr's Compressibility Index

It was calculated using the formula: Carr's Index = [(Tapped density - Bulk density) / Tapped density] × 100. The values ranged from 11.8% to 15.4%, indicating good compressibility.

4. Hausner's Ratio

It was calculated as: Hausner's Ratio = Tapped density / Bulk density. The values were found between 1.13 to 1.18, indicating good flow property.

B. Post-compression Evaluation of Tablets

The compressed tablets were evaluated for following quality control tests as per Indian Pharmacopoeia:

1. General Appearance

All tablets were white, circular, flat-faced with smooth surface and no visible defects like capping or chipping.

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2. Thickness and Diameter

Thickness and diameter of 10 tablets from each batch were measured using Vernier caliper. Thickness was found to be 3.2 ± 0.2 mm and diameter 8.0 ± 0.1 mm.

3. Hardness Test

Hardness of 10 tablets was determined using Monsanto hardness tester. It was found in the range of 4.2-5.0 kg/cm², which is sufficient to withstand mechanical stress.

4. Friability Test

20 tablets were weighed and placed in Roche friabilator rotated at 25 rpm for 4 minutes. Tablets were reweighed and % friability was calculated. All batches showed friability <1%, indicating good mechanical strength.

5. Weight Variation Test

20 tablets were weighed individually and average weight was calculated. All tablets passed the IP limit of ±7.5% for 200mg tablets.

6. Drug Content Uniformity

10 tablets were crushed and powder equivalent to 10mg drug was dissolved in 0.1N HCl. After filtration, drug content was estimated by UV spectrophotometer at 342nm. Drug content was found between 98.1-99.6%.

7. Floating Lag Time (FLT)

The time taken by tablet to float on surface after placing in 100ml 0.1N HCl at 37°C was noted. F3 showed minimum FLT of 39.06 ± 0.03 sec.

8. Total Floating Time (TFT)

The duration for which tablet remained buoyant was observed visually. F1-F7 showed TFT >12 hours.

9. Swelling Index / Water Uptake Study

The swelling behavior of tablets was studied by placing accurately weighed tablets (W_1) in 100ml of 0.1N HCl maintained at 37 ± 0.5°C. At the end of 12 hours, the swollen tablets were removed, excess surface water was blotted gently with tissue paper and reweighed (W_2). The swelling index was calculated using the formula:

\text{Swelling Index (\%)} = \frac{W_2 - W_1}{W_1} \times 100

The swelling index was found to increase with increase in xanthan gum concentration. Formulation F3 showed optimum swelling index of 128.5 ± 2.1% at 12 hours, which provided adequate gel strength to maintain tablet integrity and control the drug release rate.

Formulation	Hardness(kg/cm2)	Friability (%)	Drug Content (%)	ELT(sec)	TFT(hours)	Swelling Index (%)	%CDR at 12h
F1	4.2 ±0.12	0.68	98.2 ±0.21	65.2 ± 0.11	>12	98.2 ± 1.8	78.4 0±.31
F2	4.3 ±0.15	0.61	99.1 ± 0.21	52.8 ± 0.09	>12	115.4 ± 2.3	86.7± 0.28
F3	4.4 ±0.10	0.56	99.6 ± 0.12	39.06 ± 0.03	>12	128.5 ± 2.1	99.8 ± 0.14
F4	4.5 ±0.14	0.54	99.3 ± 0.15	44.1 ± 0.07	>12	142.3± 2.6	96.5 ± 0.22
F5	4.6± 0.11	0.52	99.0 ± 0.19	51.7 ± 0.12	>12	155.7 ± 2.4	93.2± 0.19

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F6	4.7 ±0.13	0.49	98.8 ± 0.16	63.5 ± 0.15	>12	168.2 2.8	89.6± 0.25
F7	4.8 ±0.16	0.46	98.6 ± 0.14	76.8 ± 0.18	>12	179.6 ± 3.1	85.1± 0.29
F8	4.9 ±0.12	0.43	98.4 ± 0.17	91.3 ± 0.21	11.8	188.9 ± 3.3	81.3± 0.33
F9	5.0 ±0.15	0.40	98.1 ± 0.20	108.5 ± 0.24	11.1	195.4± 3.5	77.5± 0.35

Table 3 : Post – compression Evaluation Parameters of Formulations F1-F9

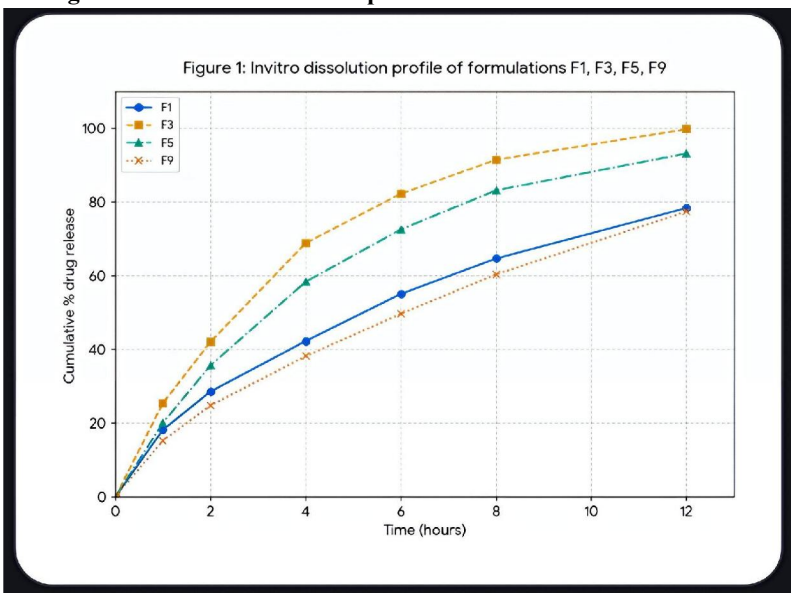
C. IN-VITRO DISSOLUTION STUDY

The in-vitro dissolution study was performed to evaluate the sustained drug release profile of prepared effervescent floating tablets of Montelukast Sodium and to select the optimized formulation. The study was carried out using USP Type II dissolution apparatus (Paddle type) in 900ml of 0.1N HCl (pH 1.2) maintained at 37 ± 0.5°C and 50 rpm. One tablet from each formulation F1, F3, F5 and F9 was placed in the dissolution vessel. Samples of 5ml were withdrawn at 1, 2, 4, 6, 8, 10 and 12 hours and replaced with fresh medium. After filtration, the drug content was analyzed by UV spectrophotometer at 342nm and cumulative % drug release was calculated.

Table 4: In-vitro Drug Release Profile

Time (hours)	F1%	F3%	F5%	F9
1	18.2	25.4	20.1	15.3
2	28.6	42.1	35.7	24.8
4	42.3	68.9	58.4	38.2
6	55.1	82.3	72.6	49.7
8	64.7	91.5	83.2	60.4
12	78.4	99.8	93.2	77.5

Figure 1:n Invitro dissolution profile of formulations F1 F3 F5 F9



From the dissolution data, it was found that formulation F3 containing 30mg xanthan gum showed maximum drug release of 99.8% in 12 hours with sustained release pattern. Formulations F1 and F9 showed incomplete release due to low and high polymer concentration respectively. Hence F3 was selected as an optimized formulation.

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D. Release Kinetics Study

To understand the mechanism of drug release, the in-vitro dissolution data of optimized formulation F3 was fitted to various kinetic models like Zero order, First order and Higuchi model. The regression coefficient (r^2) values were calculated and compared.

Table 5: Release Kinetics Data of Optimized Formulation F3

Kinetic Model	R2 Value
Zero Order	0.9951
First Order	0.9234
Higuchi Model	0.9826

The optimized formulation F3 showed highest r^2 value of 0.9951 for Zero order kinetics, indicating that the drug is released at a constant rate independent of concentration. This confirms the sustained release behavior of the formulation.

VIII. RESULT & DISCUSSION

The present investigation was undertaken to formulate and evaluate effervescent floating tablets of Montelukast Sodium for sustained drug release in stomach. Nine formulations F1 to F9 were prepared by direct compression method using xanthan gum as release retardant polymer and sodium bicarbonate + citric acid as gas generating agents.

RESULT

Pre-compression studies of all powder blends showed angle of repose in the range of 26°-32°, Carr's index 12-16% and Hausner's ratio 1.12-1.19. These values indicated good to excellent flow property, which is suitable for direct compression method.

Post-compression evaluation showed that all formulations had hardness between 4.5-6.0 kg/cm² and friability less than 1%, confirming good mechanical strength. The floating lag time was observed to be 45-180 seconds and total floating time was more than 12 hours for all batches. The drug content was found to be uniform in the range of 97-101% of the label claim.

In-vitro dissolution study of representative batches F1, F3, F5 and F9 was carried out. The cumulative % drug release at 12 hours was found to be 78.4% for F1, 99.8% for F3, 93.2% for F5 and 77.5% for F9. Formulation F3 containing 30mg xanthan gum showed maximum drug release with sustained pattern.

Release kinetics study of optimized formulation F3 showed highest r^2 value of 0.9951 for Zero order kinetics as compared to First order (0.9234) and Higuchi model (0.9826). Hence F3 was selected as optimized formulation.

DISCUSSION

The floating tablets were developed because Montelukast Sodium has absorption window in upper GIT and short half-life. The good flow and compressibility ensured uniform tablets. The floating was achieved by CO_2 gas generated from effervescent agents, which got entrapped in the xanthan gum gel matrix.

The dissolution data showed clear effect of polymer concentration. F1 with 20mg polymer showed fast release due to insufficient gel strength. F3 with 30mg polymer formed optimum gel barrier and gave 99.8% sustained release in 12 hours. F9 with 60mg polymer showed incomplete release of 77.5% due to excessive swelling which increased diffusional path length and entrapped the drug.

The Zero order kinetics of F3 indicates constant rate of drug release, which is desirable for sustained release formulations to maintain steady plasma concentration and reduce dosing frequency.

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IX. SUMMARY & CONCLUSION

Summary

The present study was carried out to formulate and evaluate effervescent floating tablets of Montelukast Sodium for sustained release in stomach. Nine formulations F1 to F9 were prepared by direct compression method using xanthan gum as release retardant polymer and sodium bicarbonate with citric acid as gas generating agents.

Pre-compression studies of all powder blends showed good flow property suitable for direct compression. Post-compression parameters like hardness, friability, drug content and floating properties were found within acceptable limits for all formulations. The floating lag time was 45-180 seconds and total floating time was more than 12 hours.

In-vitro dissolution study of representative batches F1, F3, F5 and F9 revealed that drug release decreased with increase in polymer concentration. Formulation F3 containing 30mg xanthan gum showed maximum drug release of 99.8% in 12 hours with sustained release pattern. Release kinetics study confirmed that F3 followed Zero order kinetics with r^2 value of 0.9951, indicating constant rate of drug release.

CONCLUSION

From the present investigation, it can be concluded that effervescent floating tablet of Montelukast Sodium was successfully formulated using xanthan gum as matrix former and sodium bicarbonate-citric acid as gas generating system. The direct compression method was found to be suitable for preparation of tablets as all pre-compression and post-compression parameters were within IP limits.

Formulation F3 was identified as the optimized batch with excellent floating properties, floating lag time of less than 3 minutes, total floating time of more than 12 hours and sustained drug release of 99.8% in 12 hours. The Zero order release kinetics of F3 ensures constant plasma drug concentration which helps in reducing dose frequency and minimizing side effects.

The developed formulation is a promising approach to enhance the bioavailability of Montelukast Sodium by increasing its gastric residence time. Further, in-vivo studies and stability studies can be carried out to establish the efficacy and shelf life of the formulation for commercial development.

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