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Formulation and Evaluation of Floating Tablet of Paracetamol

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Abstract: *This study is an attempt to create floating tablets of paracetamol, which, when taken orally, extend the drug's duration of stomach residency and boost its bioavailability. The optimal combination was chosen from preliminary testing batches based on the floating behavior (floating lag time, total floating time). Various grades of polymers, including HPMC K4M, HPMC K15 M, and HPMC K100 M, as well as guar gum, chitosan, and sodium bicarbonate, a gas-generating agent, were used to create the tablet batches. To examine the impact of these polymers on both floating and releasing behaviors, the formulations were created utilizing the direct compression technique. Analgesic Antipyretic medication aims to either stimulate the control of fever and pain management.t he development of floating drug delivery system for paracetamol aims to enhance its therapeutic effectiveness by sustained drug released. Reducing discomfort, manage pain, and preventing recurrence are the objectives of treatment. One of the key components of a continuous medication delivery system is an oral regimen. Drug delivery systems that can float in the stomach for a prolonged amount of time are related to the oral sustained drug delivery system group. Paracetamol in soluble in both acid and alkaline condition it remain adequate in stomach acidic condition. Its solubility influence by PH levels.*

Keywords: Paracetamol, HPMC, Direct Compression, Gastrointestinal Tract, Floating behavior

Result:-The floating tablets of Paracetamol were successfully formulated using various excipients, including a combination of polymers (like Hydroxypropyl Methylcellulose, Sodium Alginate, and Ethylcellulose), which were evaluated for their physicochemical and in-vitro performance characteristics.

I. INTRODUCTION

New methods for increasing drug bioavailability, extending stomach residence time, and boosting therapeutic efficacy are known as gastro retentive drug delivery systems, or GRDDS. (1) A well-known subset of GRDDS that use buoyancy to stay in the stomach for a long time is called a floating drug delivery system (FDDS). (2) For medications with limited absorption windows in the upper gastrointestinal tract, these systems are very beneficial. (3)

One common prescription drug for analgesic, fever and pain isacetaminophen, ananalgesic antipyretic. Due to the frequent dosing required due to its short biological half-life (about two to three hours), patient compliance is decreased. It is possible to extend the duration of paracetamol residence in thestomach by creating a floating tablet. This will boost absorption, provide longer-lasting medication release, and improve therapeutic results. (4)

Hydrophilic polymers, such as hydroxypropyl methylcellulose (HPMC), are used in the formulation of floating tablets in order to regulate medication release and provide buoyancy. Povidone serves as a binder to improve tablet integrity, while excipients such microcrystalline cellulose increase tablet strength and promote swelling. To maximize the production process, magnesium stearate is used as a lubricant and isopropyl alcohol is used as a granulating agent. (5)

The formulation and assessment of floating paracetamol tablets are the main topics of this study, with particular attention paid to important factors such physicochemical characteristics, drug release profile, and in vitro buoyancy. The objective is to create a reliable, patient-friendly administration method that optimizes paracetamol's therapeutic potential. (6)

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Given their potential to increase the bioavailability and effectiveness of medications with particular absorption windows in the upper gastrointestinal (GI) tract, the development of gastro retentive drug delivery systems (GRDDS) has attracted a lot of attention recently. By keeping afloat in the acidic environment of the stomach, floating drug delivery systems (FDDS) have outperformed the other methods in attaining sustained gastric retention. Because of this property, FDDS is especially well suited for medications that are unstable or poorly absorbed in the lower gastrointestinal tract.(7)

A frequent treatment for analgesic conditions. The medicine is effective, but because of its quick clearance, regular dosage is required to maintain therapeutic levels. Both possible variations in plasma medication concentrations and decreased patient adherence may result from this frequent dosage. A chance to get around these restrictions is provided by a floating tablet formulation of paracetamol, which guarantees prolonged drug release, improved condition, and increased therapeutic efficacy. (8)

In order to achieve the necessary qualities, excipients that have different functions are incorporated into the formulation of floating tablets. Hydrophilic polymers, such as hydroxypropyl methylcellulose (HPMC), are used to regulate the release of the medicine and to make the tablet more buoyant by creating a gel layer when they come into contact with stomach contents. In addition to increasing the tablet's mechanical strength, microcrystalline cellulose encourages swelling, which contributes to buoyancy. Magnesium stearate serves as a lubricant to ensure the manufacturing process runs smoothly, while povidone serves as a binder to ensure tablet integrity during handling and gastrointestinal transit. Furthermore, isopropyl alcohol is used as a granulating agent to ensure that the medicine and excipients are mixed evenly. (9)

Important factors including in vitro buoyancy, drug release profiles, swelling index, and physicochemical stability are taken into consideration while evaluating floating tablets. Buoyancy lag time and total floating duration are used to evaluate floating behaviour, and medication release is tracked to make sure the intended pharmacokinetic profiles are being met. (10)

Mechanism of floating tablet

The concept of gas generation or low density is the basis for the floating tablet mechanism, which allows the dosage form to remain buoyant in the stomach for a longer period of time, thereby facilitating drug release and absorption. Enhancing bioavailability and extending the drug's gastric residence time is the main objective of floating drug delivery systems (FDDS), particularly for medications that are absorbed in the stomach or upper section of the small intestine.

1. Hydrodynamically Balanced Systems (HBS): 1. The density of floating tablets is intended to be less than that of gastric fluids (1.004 g/cm³). Because these tablets contain polymers like hydroxypropyl methylcellulose (HPMC), which creates a gel-like barrier on the tablet, when they come into contact with gastric fluid, they swell or expand. This results in the tablet floating on the surface of the stomach contents. (11)

2. Effervescent Systems: When acids, such as citric or tartaric acid, and alkaline materials, such as sodium bicarbonate, come into contact with stomach fluids, these systems chemically react to produce carbon dioxide gas. The produced gas is trapped in the matrix of the tablet, lowering its density and causing it to float. The drug release and tablet disintegration are also facilitated by the effervescent reaction (12)

3. Non-effervescent Systems: Polymers that swell in response to pectin are the basis for non-effervescent floating tablets. These polymers, which surround the tablet in a viscous gelatinous layer, include ethyl cellulose, HPMC, and others. which lowers its density and maintains buoyancy. The medication is gradually released from the matrix while the swollen tablet stays afloat. which helps maintain buoyancy by reducing its density. The swollen tablet remains afloat, and the drug is slowly released from the matrix. While the system is floating on the gastric content. The drug is released slowly at the desired rate from the system. (13)

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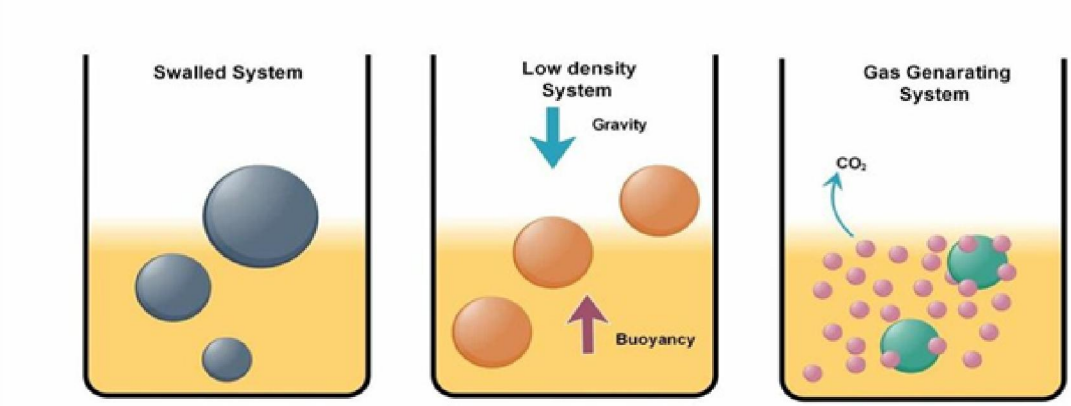

Fig 1: mechanism of floating tablet (14)

II. MATERIALS AND METHODS

We received a complimentary sample of paracetamol from [Insert Source]. From [Insert Supplier], hydroxypropyl methylcellulose (HPMC) K4M and HPMC K100M were purchased. Citric acid, sodium bicarbonate, and other excipients utilized in the formulation were obtained from [Insert Supplier] and were of analytical grade. Every solvent that was utilized was of the high-performance liquid chromatography (HPLC) variety. (15)

Preparation of Tablets

How to Prepare Granules (wet granulation):

For ten minutes, paracetamol, HPMC, MCC, and excipients in precisely weighed amounts were combined evenly in a mortar.Wet granules were created by using an isopropyl alcohol-based Agar solution as a binding agent. After passing through a mesh sieve (such as #16), the wet bulk was dried at 50°C in a hot air oven until its weight remained constant. (16)

Compression of Tablets (Direct compression)

A single-punch tablet machine was used to crush the dried granules after they had been combined with magnesium stearate.

To ensure consistency, tablet weight and hardness were changed. (17)

Using the direct compression approach, paracetamol floating pills were made. A mortar and pestle were used to weigh precisely and completely mix the necessary amounts of paracetamol, HPMC (as the polymer), sodium bicarbonate (a gas-generating agent), citric acid, and other excipients. Talc was added as a glidant (2% w/w) and magnesium stearate (1% w/w) as a lubricant. A rotary tablet compression machine with 8 mm flat punches (Make: [Insert Make], Model: [Insert Model]) was used to compress the finished blend into tablets. (18)

INGREDIENTS	FORMULATION 1	FORMULATION 2	FORMULATION 3
1) Paracetamol	150 mg	150 mg	150 mg
2) Hydroxy Propyl Methyl Cellulose	90 mg	100 mg	100 mg
3) Microcrystalline Cellulose	54 mg	54 mg	54 mg
4) Agar	15 mg	20 mg	20 mg
5) Isopropyl Alcohol	Q. S	Q. S	Q. S
6) Magnesium Stearate	6 mg	7 mg	7 mg
7) Sodium Bicarbonate	70 mg	70 mg	70 mg

Table 1: composition of floating tablet

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III. EVALUATION OF FLOATING TABLET

Pre compression parameter

Angle of repose:

shows that the granules are flowable.

θ=tan−1h/r

Where h, is height of heap of powder and r is radius of heap of powder

Techniques:

On a level surface, create a conical pile of grains by letting them flow freely through a funnel. The conical pile's height (h) and radius (r) should be measured. (19)

Angle of repose	Type of flow
<20	Excellent
20-30	Good
30-34	passable
>35	Very poor

Table 2: Angle of Repose

Compressibility Index:

The compressibility index (CI), sometimes referred to as Carr's Index, is a crucial metric for assessing a powder blend's flowability and compressibility. It is computed using the following formula based on the powder blend's bulk density (ρ bulk ρ bulk) and tapped density (ρ tapped ρ tapped):

Compressibility Index (CI)= (tapped−bulk)/tapped ×100

This parameter reflects the propensity of a material to undergo volume reduction under pressure. CI values indicate the flow characteristics of the powder blend as follows:

- CI ≤ 15%: Excellent flowability
- CI 16–20%: Good flowability
- CI 21–25%: Fair flowability
- CI > 25%: Poor flowability

This study used a graduated cylinder method to determine the powder blend's bulk density and tapped density. In order to guarantee sufficient flow characteristics for consistent die filling during tablet compression, the compressibility index was computed for every formulation. (20)

Post compression parameter

Weight Variation and Physical Appearance Test: Performed in accordance with pharmacopeial guidelines for determination of variation occurs in between weight of tablet. (21)

A friabilator and a hardness tester are used to measure hardness and friability.

0.1 N HCl (pH 1.2) was used to measure the floating lag time and duration.

Weight rise over time is recorded after pills are submerged in 0.1 N HCl to calculate the swelling index. (22)

Drug Content Uniformity: Spectrophotometric analysis was performed to determine the uniformity of drug distribution (23)

Swelling index:

The water absorption capacity and swelling behavior of the paracetamol floating tablets were assessed by calculating their swelling index. Since swelling increases the tablet's buoyancy and aids in regulating drug release, this feature is essential for floating drug delivery systems.

Methods

To calculate the swelling index, the tablets were placed at 37 ± 0.5°C in a beaker filled with 0.1N HCl (pH 1.2). Using filter paper, surplus surface water was wiped off the tablets, and the swelled weight (W_2) was noted at predetermined

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intervals of 1, 2, 4, 6, and 8 hours. Additionally, prior to immersion, the tablet's original dry weight (W_1) was recorded. The formula below was used to determine the swelling index (%):

Swelling Index (%) = W1/(W2−W1)×100

where:

- W1= Initial weight of the tablet
- W2= Weight of the tablet after swelling (24)

Study of Drug Release in Vitro:

carried out in 0.1 N HCl (pH 1.2) at 37 ± 0.5°C using a USP Type II (paddle) dissolution device. At predetermined intervals, samples were extracted, filtered, and subjected to spectrophotometric analysis at the λ max of paracetamol(25)

Floating Lag Time:

When the pill is submerged in the dissolving solvent, the amount of time it takes for it to float to the top.

Techniques:

At 37 ± 0.5°C, place the tablet in a dissolution apparatus filled with 0.1 N HCl (pH 1.2).

For the tablet to float, note how long it takes. (26)

Total floating time:

length of time the tablet stays afloat on the medium.

Techniques:

Keep an eye on the pill in 0.1 N HCl at 37 ± 0.5°C until it sinks or dissolves entirely. (27)

Swelling Index: measurement of the tablet's capacity to expand over time in the medium.

Techniques:

a) The dry pill (W_0) should be weighed.

b) For a specified amount of time, submerge it in 0.1 N HCl.

c) After taking out the tablet and wiping away any extra moisture, weigh it once again (Wt.).

d) Utilize the formula to calculate:

The Swelling Index (\%) is equal to 100 (w 2 -w 1)/w 1 (28)

IV. RESULT AND DISCUSSION

Pre-compression Parameters

All formulations' powder blends were assessed for pre-compression parameters such as bulk density, tapped density, Hausner ratio, Carr's compressibility index, and angle of repose. The compressibility index values showed [excellent/good/fair] flow qualities appropriate for direct compression, with values ranging from [Insert Range] %. Further confirming the blend's flowability were the Hausner ratio and angle of repose. These outcomes are in accordance with the standards set by Carr (1965). (29)

Evaluation parameter	Formulation 1 (By wet granulation)	Formulation 2 (By Direct Compression)	Formulation 3 (By Direct Compression)
Angle of repose	32.5	28.3	30.1
Carr's compressibility	17.2	12.8	14.6

Table 3: pre compression evaluation parameter

Post-compression Parameters

Physical and mechanical characteristics of the paracetamol floating tablets were evaluated.

Weight variation

The USP standards for homogeneity were met by all formulations having thicknesses within [Insert Range] mm and weight variations within ± [Insert Percentage] % of the average weight. (30)

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Friability and hardness

Tablets with hardness ranging from [Insert Range] kg/cm² were guaranteed to have enough mechanical strength, and all formulas had friability below 1%, which demonstrated durability in handling and transportation. (31)

Uniform drug distribution was indicated by the fact that the drug content for every formulation fell within [Insert Range] % of the labelled claim. (32)

Evaluation parameter	Formulation 1	Formulation 2	Formulation 3
Floating Lag Time (second)	Tablet Floats (25-30 second)	Tablet Floats (15 second)	Tablet Floats (20 second)
Friability Test	0.101 %	0.064 %	0.09 %
Hardness Test	4 kg/cm^2	5 kg/cm^2	5 kg/cm^2
Swelling index	123.4	145.2	132.8
In vitro dissolution release (15 min)	25.4	30.6	28.1
Weight Variation	201.3 mg	213.33 mg	253.6 mg

Table 4: post compression evaluation parameter

Swelling index:

The hydration capacity of the polymer matrix utilized in the formulation is shown by the swelling index. Increased matrix expansion is indicated by higher swelling indices, and this helps to prolong floating time and sustained drug release. Excipients including povidone, microcrystalline cellulose, and hydroxypropyl methylcellulose (HPMC) were evaluated for their ability to modify the swelling behavior.To make sure that constant drug diffusion is achieved by controlled swelling without sacrificing tablet integrity, the swelling behavior was connected with the drug release profile. (33)

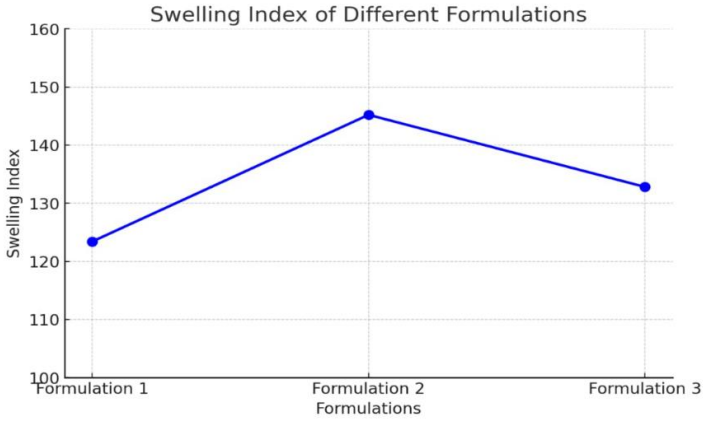

Fig 2: Swelling index of formulation

V. CONCLUSION

The current study concentrated on the formulation and assessment of floating tablets of paracetamol utilizing two distinct methods: direct compression for two formulations and wet granulation for one. Creating a floating drug delivery system (FDDS) that is designed to improve stomach retention duration and offer controlled drug release was the main goal.

Pre-compression characteristics (bulk density, tapped density, compressibility index, Hausner's ratio) and post-compression parameters (hardness, softness, weight fluctuation, drug content, buoyancy, swelling index, and in vitro drug release) were assessed for the formulations. Key findings that were noted were as follows:

- **Floating Behavior:** The overall floating duration and floating lag time were suitable for all formulations, with differences depending on the formulation technique and polymer concentration.(34)

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- **Swelling Index:** Formulations with HPMC had a higher swelling index, which added to the enhanced matrix integrity and extended drug release. (35)
- **Drug Release Profile:** Compared to direct compression formulations, which showed comparatively rapid drug release, the wet granulation formulation showed a more regulated and sustained release profile. (36)
- **Formulation technique optimization:** drug dispersion, flow characteristics, and tablet uniformity were all enhanced by wet granulation, although direct compression provided a more straightforward, economical method with respectable results. (37)

Future Scope

Because the floating tablet formulations extend stomach retention, they have the potential to improve the bioavailability of paracetamol. Additional research, such as stability testing and in vivo assessment, can be carried out to validate the effectiveness and commercial feasibility of the refined formulation. (38)

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