

Sustained Release Floating Drug Delivery System for Muscle Relaxant

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Abstract

Oral medication delivery is the most popular method of administration since it is noninvasive, has a high patient compliance rate, is easy to handle, and does not require any special sterile conditions. However, some medications taken orally meet a number of physical, biological, and biochemical hurdles that reduce their therapeutic efficacy before they are absorbed into the bloodstream. Muscle relaxants, which are often used to treat spasticity and musculoskeletal diseases, must be administered at consistent therapeutic doses to ensure long-term efficacy and minimise side effects. Sustained and floating drug delivery systems offer a promising strategy for enhancing oral drug bioavailability by prolonging gastric residence time and enabling site-specific drug release. This review examines the key materials used in GRDDSS, including polymers for controlled drug release, gas-generating agents for buoyancy, and mucoadhesive components for improved retention and stability.

By enhancing the medicine's buoyancy over the stomach fluids, the floating drug delivery system (FDDS) helps to sustain the extended duration of action. It helps reduce the frequency of dose. In FDDS, the density of the dose form must be lower compared to the density of gastric contents (1.004 gm/ml). Both effervescent and non-effervescent systems are possible. The floating drug delivery device is a suitable fit for medications with a limited GIT absorption window.

This review article's primary goal is to gather recent research with an emphasis on classification, methods of preparation, and the benefits and downsides of mechanisms of action. This review summarizes the limitations of conventional oral dosage forms, the rationale for sustained-release and gastroretentive floating systems, and recent advancements in formulation approaches for muscle relaxant delivery. Emphasis is placed on formulation design considerations, mechanism of floatation, and in-vitro evaluation techniques. The review highlights the potential of sustained-release floating tablets as an effective oral delivery strategy for improving therapeutic outcomes and patient compliance in muscle relaxant therapy.

Keywords : Sustained Release, Floating drug delivery system, Gastroretentive System, Oral drug delivery, muscle relaxants.

INTRODUCTION

Spasticity is a widespread neurological condition with several causes, including stroke, multiple sclerosis, tumours, hypoxic brain damage, cerebral palsy, and traumatic brain injury. Spasticity, as traditionally defined, is a velocity-dependent increase in muscle tone caused by an exaggeration of the stretch reflex. Spasticity can be a complex illness to address, thus it requires a multi-team approach with the participation of physical therapists, occupational therapists, clinicians, and careful family planning.[1,2]. Spasticity can be disabling. It can be activated at any time by a variety of stimuli. External causes such as constipation, urinary tract infections, and pressure ulcers can worsen spasticity and accompanying symptoms.[3,4] Spasticity can also have functionally limiting and painful consequences, such as decreased joint mobility, reduced muscle flexibility, and sleep difficulties caused by airway constriction. [5] The location of spasticity is determined by a lesion in the central nervous system. It usually manifests in the lower back and legs[6], but upper body spasticity or discomfort is also prevalent. Untreated spasticity can cause abnormalities such as kyphoscoliosis and contractures, which are difficult to repair. [3]

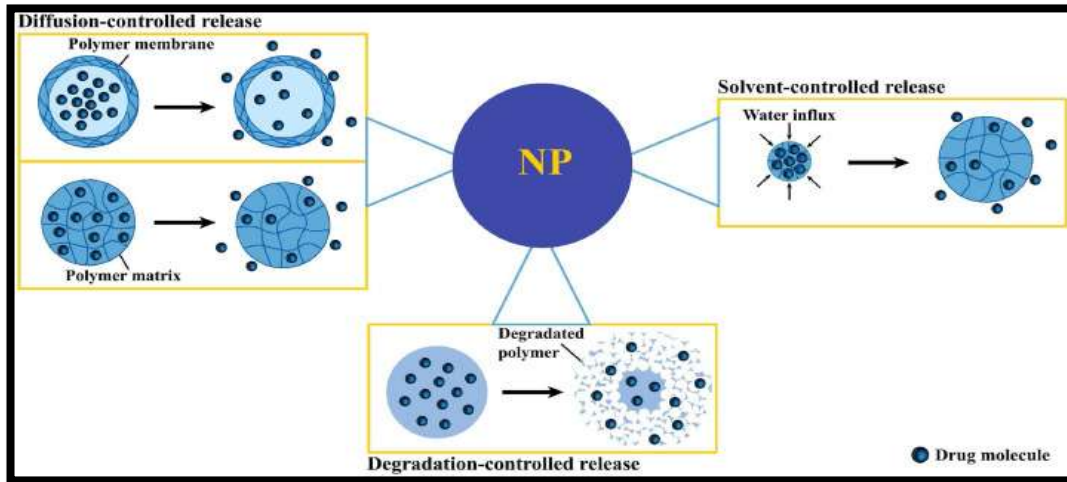
Sustained Release drug delivery system

These abnormalities can significantly complicate regular tasks. Patients and medical professionals frequently like the oral route of medication delivery since it is convenient, simple to administer, non-invasive, and well-received by patients. However, there are a number of drawbacks to conventional oral dosage forms, such as reduced bioavailability, restricted drug loading capacity, and stability and storage problems, especially with solutions and suspensions. To get over these restrictions, scientists have worked hard over the years to create innovative oral medication delivery methods. This review covers a number of issues related to oral drug delivery methods, including as physicochemical, pharmacological, and biological barriers. Oral medication delivery is the most often used way for delivering drugs through pharmaceutical goods in various dosage forms [7] Sustained release pills are often given once or twice a day throughout a treatment period, whereas conventional dosage forms require three to four doses per day to accomplish the same therapeutic impact. Sustained release dosage forms allow for a single dose of a drug to be released over time, resulting in a consistent concentration of the drug in the blood. This can improve patient compliance and clinical outcomes.[8]

Rational for development of SRDDS

1. Formulations of SRDDS minimize dosing frequency and sustained release provides availability of a drug at action site throughout the treatment to improve clinical efficiency of a drug molecule.
2. To reduce cost of treatment by reducing number of dosage requirement.
3. To minimize toxicity due to overdose which is often conventional dosage form.

4. To enhance the activity duration of a drug possessing short half-life.[7.9]



Sustained drug release Fig no :1

Floating drug delivery system

gastro-floating drug delivery method is one of the most promising dosage forms among the gastroretentive dosage forms because it has a lower impact on gastrointestinal tract (GIT) motility.[13] This is because the irregular gastric residence time of dosage forms causes variations in plasma drug concentration, which is why gastro-floating dosage forms are preferably used to reduce the variations of gastric residence time.[10,11]. This variability may lead to unexpected bioavailability and times to achieve peak plasma levels because the majority of drugs are absorbed in the upper part of the small intestine. [12]Drug absorption from the gastrointestinal tract is a complex and varied process. The amount of medication absorbed through the gastrointestinal system is known to be influenced by the length of contact with the mucosa of the small intestine [13,14]. Therefore, when assessing drugs that are not completely absorbed, little intestinal transit time is an important consideration. Juices are produced in the stomach. The retentive properties of the dose form are meaningless for drugs that act locally, are insoluble in stomach juices, or exhibit site-specific absorption. [15].The drug known as FDDS is made using hydrocolloids that form a gel and are meant to remain buoyant in the stomach's contents. Drug degradation and release from the dosage form occur in the gastrointestinal tract's pH under somewhat regulated conditions.

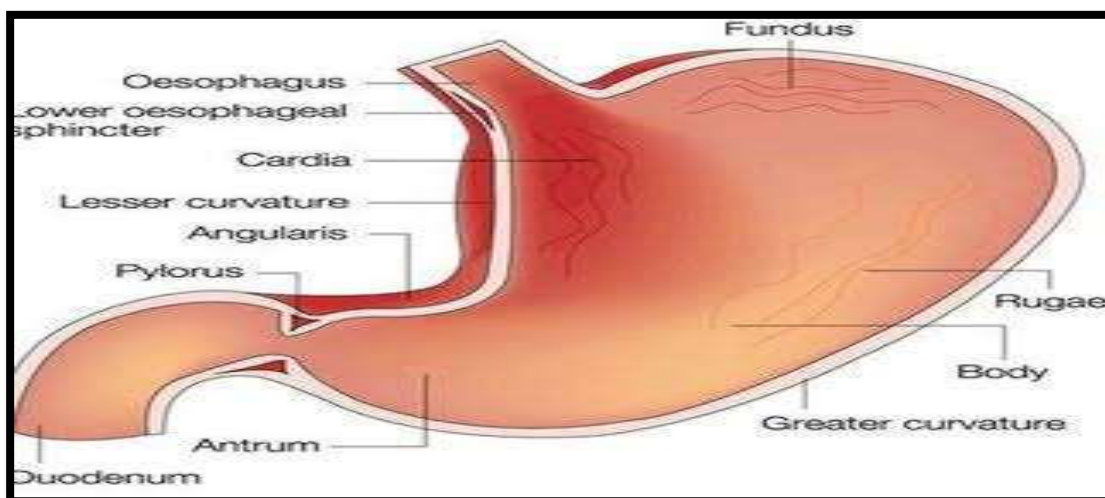
Advantage of FDDS



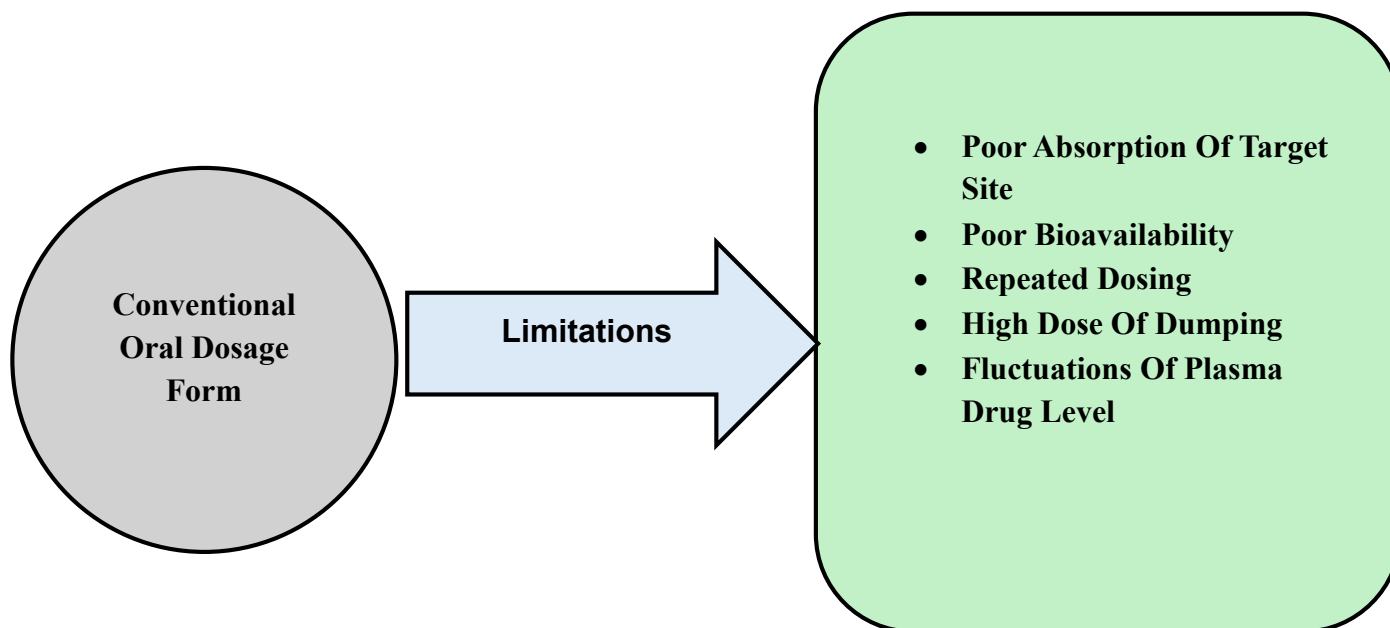
Floating drug delivery system Fig no :2

PHYSIOLOGY OF STOMACH

FDDS benefits these drugs by enhancing them. Bioavailability effectiveness of treatment and potential dose reduction. Long-term preservation of therapeutic levels at the same level results in reduced variance in therapeutic levels. Reduces drug waste and boosts pharmaceutical solubility. The fundus and body serve as reservoirs for undigested materials because they are less soluble in high pH environments.



Limitation of conventional oral dosage forms



Physiology of stomach no: 3

Rationale For Sustained Drug Delivery system

Sustained release dosage forms are designed to minimise side effects by releasing medication at a specific rate while maintaining a steady drug level for a predetermined amount of time. The basic idea behind sustained-release drug delivery systems is to increase the bioavailability and efficacy of the medications in order to improve patient compliance.

| Advantages | Disadvantages |
|--|--|
| Total Dose Is Low | Dose Dumping |
| Reduce GI Side effects | Reduce potential for accurate Dose Dumping |
| Less Fluctuation Of Plasma Drug Level | Stability problem |
| Better patient acceptance and compliance | Need Of Additional Patience Compliance |

Floating drug delivery system

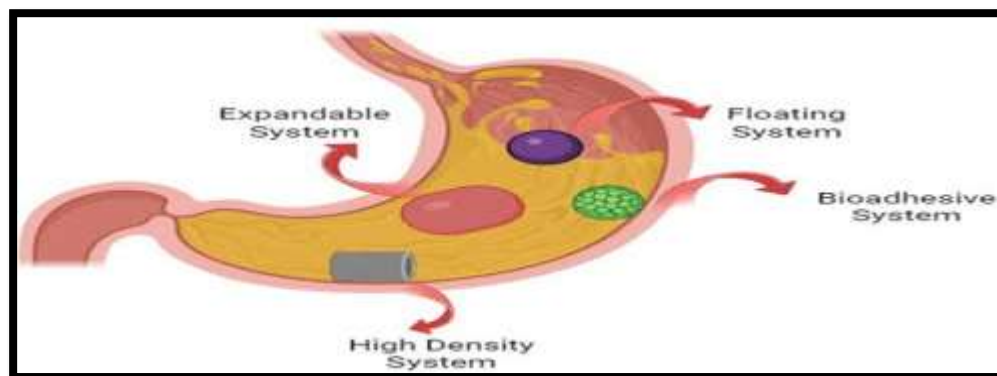
Floating Drug delivery mechanism Floating drug delivery systems (FDDS) are low-density devices with sufficient buoyancy to float over stomach contents and stay buoyant there without slowing down the rate at which the stomach discharges its contents. Because drugs can remain in the gastrointestinal region for several hours, floating delivery methods can significantly increase their stomach residency periods. Long-term stomach retention improves solubility, reduces drug waste, and boosts bioavailability for drugs that are less soluble in high pH environments. It can be used to deliver drugs directly to the stomach and adjacent small intestines. Gastro retention helps increase the availability of innovative medications that offer new treatment possibilities and substantial benefits to patients. The gastric retention of solid dose forms can be controlled by mucoadhesion, flotation, sedimentation, expansion adjustable shape systems, or concomitant delivery of pharmaceutical drugs that postpone stomach emptying.[17]

ADVANTAGE OF FDDS

- Even at the intestine's alkaline pH, floating dose forms like tablets or capsules will stay in the fluid for a long time.
- FDDS are helpful for medications designed for local action in the stomach.
- FDDS dosage forms are useful in cases of vigorous bowel movement and diarrhoea because they keep the medicine floating in the stomach, resulting in a more effective response.
- FDDS are useful for medications that are absorbed through the stomach, such as ferrous salts and antacids.
- Drugs with a relatively short half-life can be administered in this manner to achieve significant therapeutic activity.
- Increased bioavailability for medications that can be metabolised in the upper gastrointestinal tract

LIMITATION OF FDDS

- They require a significant amount of fluid in the stomach for the medicine to be buoyant, float, and function properly.
- Floating systems are not suitable for medications with poor solubility or stability in stomach fluid.
- FDDS since prolonged stomach emptying may result in lower systemic bioavailability.
- FDDS also has limits in terms of its application for medications that irritate the stomach mucosa.



Floating drug delivery system Fig no :4

Polymer And Excipients

- **Polymer**
- **Hydrophilic Polymer**

Polymer Used Because of their wide regulatory approval, cost-effectiveness, and flexibility in achieving a desired drug release profile, hydrophilic polymer matrix systems are frequently utilised in oral controlled drug delivery. In the field of controlled release, the use of hydrophilic polymers with high gelling capabilities as base excipients in the formulation of pharmaceuticals in gelatinous capsules or, more often, tablets, is particularly interesting. A well-mixed combination of one or more medications with a gelling agent (hydrophilic polymer) is known as an infected matrix. Swellable controlled release systems are the name given to these systems. Three major categories comprise the polymers utilised to create hydrophilic matrices: Ex HPMC , PVA , PVP .

- **Cellulose Derivatives** Sodium carboxy methyl cellulose with hydroxy propyl methyl cellulose
- **Soluble polymers** include PEG (polyethylene glycol), Hydroxy propyl methyl cellulose (HPMC), polyvinyl alcohol (PVA), and polyvinyl pyrrolidone (PVP)
- **Biodegradable polymers:** PLA (polylactic acid), PGA, or polyglycolic acid,
- **Mucoadhesive polymers** Carbapol 971P
- **Diluent:** When the drug dosage is insufficient to create the necessary bulk of the tablet, diluents are utilised as fillers. Better tablet qualities, such as increased cohesiveness, the ability to use direct compression manufacture, or the promotion of flow, are the secondary reasons. The following characteristics should be present in a diluent:
 - 1.They have to be safe.
 2. They ought to be of a suitable grade and commercially available.
 3. It must be inexpensive.
 - 4.They have to be inactive biologically.
 5. Both alone and in conjunction with the medications, they must be chemically and physically stable.

Ex Calcium phosphate , microcrystalline. Cellulose, , Sorbitol, Starch

- **Binders:** To create coherent tablet compacts that are crushed directly.

Ex Carboxymethylcellulose; Cellulose.

Lubricants: Lubricants are designed to lessen interparticle friction, stop tablet materials from sticking to the surface of dies and punches, and possibly increase the rate at which tablet granulation flows.

Ex Calcium Stearate. Polyvinyl Alcohol; Sodium Benzoate; Sodium Lauryl Sulfate, Stearic Acid ,Talc.

- **Glidants:** Glidants are intended to promote flow of granules or powder material by reducing the friction between the particles.

Ex Starch , Talc

Disintegrates: A substance added to a tablet formulation to help it break down or disintegrate when it comes into touch with water in the GI tract.

Ex Povidone

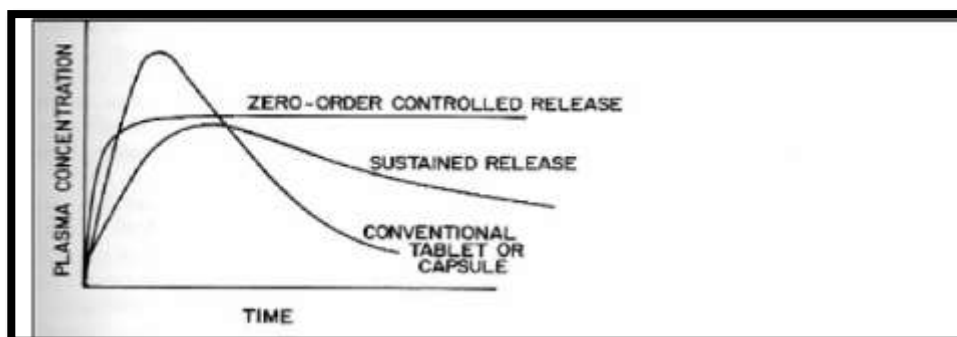
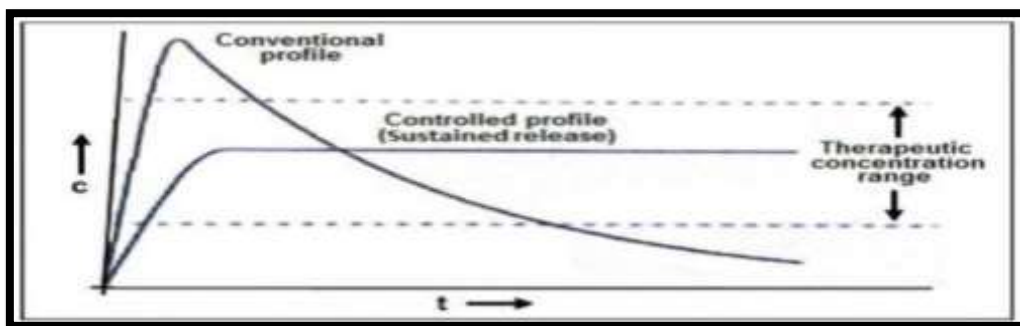
Colouring Agents: The use of colours and dyes in a tablet serves three purposes: (A) Masking of off-colour pharmaceuticals (B) Product identification (C) Creation of a more elegant product.

- **Flavouring Agents:** Flavouring oils are required for chewable pills. The oil is often applied in a dry form, such as spray-dried beadlets.
 Ex Ethyl Vanillin , Menthol [22 – 25]

Formulation Approaches: Sustained-Release Drug Delivery System

sustained release has proven to be a useful technique for managing drug release without requiring complicated manufacturing processes.[27] The majority of sustained release dosage forms use diffusion, dissolution, or a mix of the two mechanisms to generate a delayed release of the medication at a set rate. A sustained release dosage form should, in theory, release the medication by a zero-order process that keeps the drug's plasma level time comparable to intravenous infusion. Plasma drug concentration profiles for sustained release, zero order sustained release, and traditional tablet or capsule formulations.

- 1 Systems for dissolution-controlled release
2. Systems with diffusion-controlled release
3. Systems of regulated release by diffusion and dissolution
4. Drug-ion exchange resin complexes
5. Formulation based on pH
6. Systems with osmotic pressure control



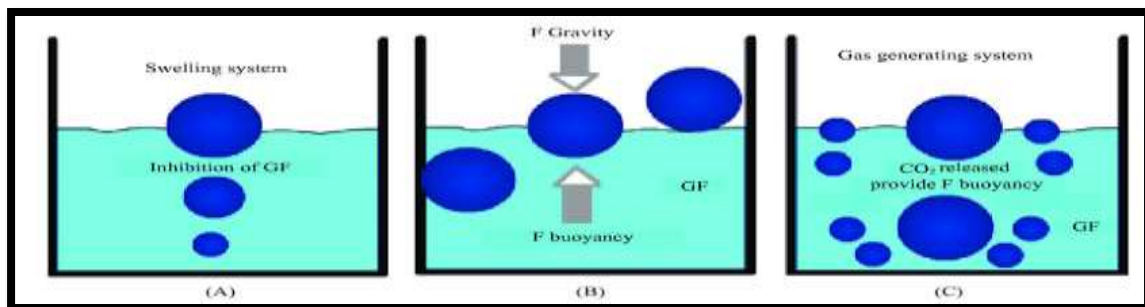
Plasma drug concentration profile for formulations with zero order-controlled release, sustained release, and conventional release.

Floating Drug Delivery System

FDDS is an effective method for increasing the drug's stomach residence duration and thus its bioavailability. FDDS are low-density systems with enough buoyancy to float over the gastric contents and remain in the stomach for a long time.[28,29] The medicine is released slowly and at the chosen rate. [30,31], While the system is floating on the gastric contents, the medicine slowly and at the desired pace exits the system. Following drug release, the stomach's residual system is emptied. This increases GRT while reducing fluctuations in plasma medication concentration. [32] Formulation of such system should reflect the following characteristics:

- 1) Sufficient structure to produce a cohesive gel barrier
- 2) Specific gravity lower than gastric fluid (1.004-1.010)
- 3) Slowly dissolve and act as a drug reservoir[33]

When floating on top of the gastric contents, floating dosage forms are located high in the stomach, closer to the fundus and further away from the pyloric aperture. The floating unit still requires a nourished stomach in order to considerably improve gastric emptying time. The flotation of the dosage form is determined by the resulting weight, which is the difference between the buoyancy force when completely immersed and the weight of the dosage form. The object will float if the resultant weight is positive. Floating medicine delivery can be generically classed as effervescent systems, Non Effervescent System.



Floating drug delivery system

Evaluation Parameter of Floating Drug Delivery System

1. **Floating duration and floating lag time** :The floating lag time and floating duration for the produced tablets were measured using the method described by Tadros [34].A 200 mL beaker filled with 0.1 N HCl at 37°C was filled with one pill. While the duration of floating was monitored visually as long as the tablet continued to float in 0.1 N HCl, floating lag time was calculated as the time it took for the tablet to reach the surface. Three repetitions of the test were run, and the outcome was averaged.

2. **Drug Release**

Drug Discharge In vitro drug release tests are often conducted in intestinal and stomach fluid simulations kept at 37 degrees Celsius. The USP dissolution device is used for dissolution tests. Samples are taken out of the dissolution medium on a regular basis, replaced with the same volume of fresh medium each time, and then their drug contents are determined after the proper dilution. According to a recent methodology outlined in USP XXIII, the dosage unit must sink to the bottom of the vessel before the blade is rotated. The

dosage units that would ordinarily float may be linked to a small, loose piece of non-reactive material, such as a few twists of wire helix.

3. Assay, Content Uniformity, Hardness, and Friability (Tablets)

These tests are carried out in accordance with the guidelines provided in particular monographs.

Application

4. In vitro buoyancy analysis

In vitro buoyancy analysis For the in-vitro floating investigation, the tablets were put in the USP type II apparatus with 900 mL of 0.1N HCl at 37.5°C and spun at 50 rpm. The floating time (FT) and FLT of each tablet formulation were recorded.[35,36]

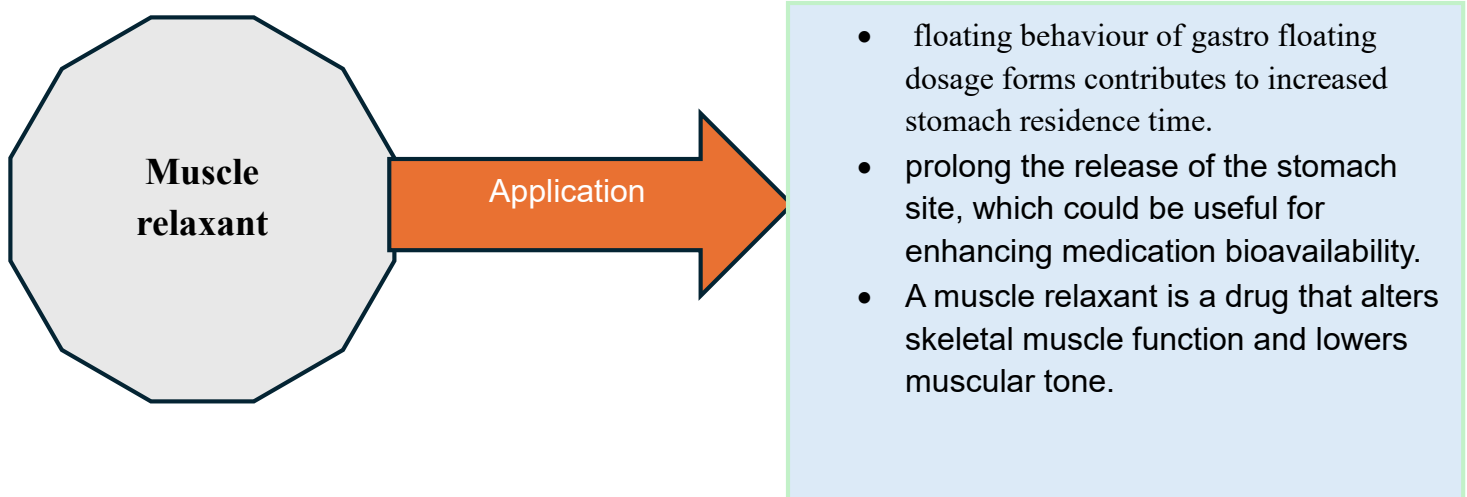
5. In-vitro dissolution study

The USP type II apparatus with 900 cc of pH 1.2 HCl was used for the in-vitro dissolution research, which was conducted at $37 \pm 0.5^\circ\text{C}$ and 50 RPM. Five millilitres of the sample were removed from the dissolution device and replaced with five millilitres of brand-new dissolution media. The samples were filtered via Whatman filter paper and then measured at 230 nm using an ultraviolet (UV) spectrophotometer.[37,38]

5. In vitro release kinetics

Release kinetics in vitro Several models, including zero-order, first-order, Higuchi, and Korsmeyer-Peppas models, were used to analyse the release kinetics. The best fitting model for the drug release was determined using the correlation coefficient.[39 ,40]

Application of muscle relaxant [41 – 42]



Conclusion

Sustained-release floating drug delivery systems provide prolonged stomach retention and regulated drug release, making them a potential strategy for oral muscle relaxant delivery. In comparison to traditional oral

dosage forms, these methods help to maintain stable plasma drug levels, minimise dosing frequency, and enhance patient compliance. Overall, floating sustained-release formulations have the potential to significantly improve the therapeutic efficiency of muscle relaxants in the treatment of muscular spasms and spasticity.

Future Perspective

Future research on sustained-release floating drug delivery systems for muscle relaxants is planned to focus on the development of new and hydrophilic polymers in order to improve drug release and stomach retention. Furthermore, the use of improved formulation technologies and clinical validation studies may enhance the therapeutic efficacy and patient compliance of floating sustained-release muscle relaxant formulations.

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