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Review Article

Gastro-Retentive Floating Drug Delivery Systems of Metformin Hydrochloride: A Comprehensive Review

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Abstract

Metformin Hydrochloride is one of the most prescribed oral antidiabetic agents in the management of Type II Diabetes Mellitus. However, its short biological half-life, incomplete gastrointestinal absorption and frequent dosing have prompted the development of advanced drug delivery systems to improve its therapeutic effectiveness. Gastro-retentive floating drug delivery systems (FDDS) have gained attention as a promising approach to prolong gastric residence time, improve drug absorption and offer sustained drug release. The present review offers a comprehensive discussion on formulation approaches, evaluation parameters, drug release mechanisms, therapeutic significance and challenges of floating tablets of Metformin Hydrochloride. Different formulation strategies using hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC), Carbopol, Sodium Alginate, Xanthan Gum, and other matrix-forming agents have been studied to achieve prolonged buoyancy and controlled drug release. This review also highlights the importance of pre-compression and post-compression evaluation parameters, such as flow properties, hardness, friability, floating lag time, total floating duration, and drug content uniformity, in ensuring the quality and performance of the formulation. In vitro dissolution studies have revealed that the type and concentration of polymers have a significant effect on the release behavior of the drug. Carbopol-based formulations often exhibit better sustained release characteristics and prolonged gastric retention. Despite great progress, there are several challenges, including variability in gastric physiology, high drug loading requirements, formulation stability, scale-up difficulties, and regulatory issues. However, available evidence indicates that floating tablets of metformin hydrochloride offer an effective gastro-retentive platform that can improve bioavailability, reduce dosing frequency, and improve patient compliance. In conclusion, floating drug delivery systems may be a potential strategy to improve oral metformin therapy and achieve better outcomes in long-term diabetes management.

One of the main symptoms of diabetes is high blood sugar or hyperglycemia. This occurs when there is a problem with insulin, either not enough is made, or the body does not use it properly. Worldwide, in 2019, approximately 9.3% of the population had diabetes, and it is projected to increase to 10.2% by 2030, and even higher at 10.9% in 2045.I think those figures are from some study. In places like India, it is a big deal. They have about 69.2 million people with type two diabetes, and it is the second most after China. It's kind of surprising how it impacts poorer countries more than rich countries[1]. The current figure for India is something like 61.2 million diabetics. That could be 101.2 million in 2030, which is a lot. Not sure why exactly the numbers are a little different like that, but anyhow, it is rising fast there. Metformin HCL is an approved first-line therapy for type II diabetes patients, as it may help lower blood glucose levels. It also seems to have a beneficial effect on plasma lipids and body weight and reduce the risk of microvascular and macrovascular complications. Metformin may be used alone or in combination with other anti-diabetic drugs[2]. It is the drug of choice for diabetes treatment, especially for type II patients. The drug has been popular for more than 40 years because of its strong ability to enhance glucose levels and address weight gain issues. However, there are challenges such as low water solubility and poor stability, which cause some drugs to have low oral bioavailability. Metformin HCl should not be taken by mouth[3]. However, despite the rapid progress in parenteral drug delivery technology, the oral route is still favored because of its convenience, low cost, painless administration, and wide acceptance by patients[4].

Scintigraphic studies of gastric emptying rates have shown that oral controlled-release dosage forms face two major problems: short gastric residence time and an unpredictable gastric emptying rate. Two different methods, effervescent and non-effervescent systems, have been employed to develop floating drug delivery systems (FDDS) based on the principle of buoyancy[5]. Effervescent drug delivery systems employ matrices of swellable polymers, such as methocel or polysaccharides, and effervescent agents, such as sodium bicarbonate and citric or tartaric acid. Floating drug delivery systems has many advantages. They are less likely to be emptied from the stomach and therefore have less variability in plasma drug levels. They are suitable for drugs with narrow absorption windows and reduce dosing frequency and improve patient compliance. They also lead to lower Cmax and higher duration of drug levels above the minimum effective concentration and hence they improve safety for drugs with side effects related to high Cmax. Metformin HCl is an antihyperglycemic biguanide that improves glucose tolerance in patients with type II diabetes[6]. It is not completely absorbed from the gastrointestinal tract. The window of absorption is limited to the upper gastrointestinal tract. It has a half-life of 1.7 hours and an absolute bioavailability of 45–50% of the dose administered, and seems to be a good candidate for a gastroretentive floating drug delivery system[7].

Floating Tablets of Metformin Hydrochloride

Much work has been published on floating drug delivery systems (FDDS) for increasing the gastric residence time and enhancing the bioavailability of metformin hydrochloride. Various techniques have been reported in the literature for the development of floating tablets, such as wet granulation, direct compression, and effervescent methods. Wet granulation is one of the most commonly used methods as it yields uniform distribution of the drug and desired tablet characteristics[8]. Different polymers, such as Hydroxypropyl Methylcellulose (HPMC), Carbopol, Sodium Alginate, and Xanthan Gum, have been used with gas-forming agents, such as sodium bicarbonate, to provide sustained buoyancy and controlled release of the drug. The choice of excipients is very important for the determination of the floating behavior, swelling characteristics, and drug release profile of the formulation[3].Pre-compression evaluation parameters were used to evaluate the quality and performance of the floating tablets. Bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio were used for pre-compression studies to evaluate the flow properties of the granules. The evaluation after compression involved the evaluation of weight variations, hardness, friability, uniformity of drug content, floating lag time, total floating duration, swelling index, and tablet integrity[9].In vitro dissolution studies are usually performed using the USP Type II (paddle) dissolution apparatus in simulated gastric fluid (0.1 N HCl, pH 1.2) to study the drug release behavior over a long period of time. In addition, in vitro buoyancy studies are conducted to measure the floating lag time (FLT) and total floating time (TFT), which are critical indicators of the gastric retention ability of floating tablets. Metformin hydrochloride optimized floating formulations have been demonstrated in many studies to maintain buoyancy for a prolonged period and achieve sustained drug release, thereby improving therapeutic efficacy and patient compliance[10].

Table 1 Summary of commonly used polymers and evaluation parameters in floating tablets of Metformin Hydrochloride

Polymer/Excipient	Primary Function	Impact on Floating Tablet Performance
HPMC (K4M/K15M/K100M)	Matrix-forming polymer	Sustained drug release and enhanced buoyancy
Carbopol 934P	Bioadhesive polymer	Improved gastric retention and swelling

Sodium Alginate	Gel-forming polymer	Enhanced matrix integrity and flotation
Xanthan Gum / Guar Gum	Natural hydrophilic polymers	Controlled drug release and swelling
Sodium Bicarbonate	Gas-generating agent	Initiates tablet flotation by CO_2 generation
Citric Acid	Effervescence enhancer	Accelerates gas production and buoyancy
PVP K-30, Magnesium Stearate & Talc	Binder, lubricant and glidant	Improves tablet strength, compression, and powder flow

3. Evaluation and Performance of Floating Tablets of Metformin Hydrochloride

Floating drug delivery systems (FDDS) have emerged as an effective approach to enhance the gastric residence time of drugs exhibiting a narrow absorption window in the upper gastrointestinal tract. Metformin hydrochloride, a first-line oral antidiabetic drug, has been extensively investigated for gastro-retentive delivery using floating tablet formulations. Various studies have demonstrated that the incorporation of hydrophilic polymers, gas-generating agents, and matrix-forming excipients significantly influences the physicochemical characteristics, buoyancy behavior, and drug release performance of floating tablets[11].

3.1 Pre-Compression Characteristics of Floating Tablet Formulations

Thus, the pre-compression characteristics of the powder blend and granules are important factors that affect the quality and efficient production of tablets. Various investigators have reported that bulk density, tapped density, Carr's compressibility index, Hausner's ratio, and angle of repose have been evaluated to determine the flowability and compressibility of granules designed for the preparation of floating tablets[12].Bulk density and tapped density provide information about the packing behavior and particle arrangement in the powder system. Optimized floating tablet formulations have been found to possess generally satisfactory density values, which in turn would be indicative of good packing properties and even die-filling during compression. Likewise, the compressibility index and Hausner's ratio are generally regarded as good powder flowability measures of Carr. The reported values within the acceptable pharmacopoeial limits indicate good flow properties and low interparticle friction, which are good for obtaining uniform tablet production[13].

Another parameter that is important for the evaluation of powder flow characteristics is the angle of repose. The angle of repose values of most of the floating tablet formulations containing metformin hydrochloride were found to be acceptable, which indicates that the tablet formulations have excellent flow behavior and are suitable for large-scale tablet manufacturing. All the results pointed towards the fact that the proper choice of polymers and excipients can play a significant role in achieving desirable pre-compression properties[14].

Table 2 Reported Pre-Compression Parameters Evaluated in Floating Tablets of Metformin Hydrochloride

Parameter	Importance
Hardness	Mechanical strength of tablets
Friability	Resistance to abrasion and shock
Weight Variation	Uniformity of tablet weight
Drug Content	Uniformity of drug distribution
Floating Lag Time	Time required to initiate floating
Total Floating Time	Duration of tablet buoyancy
Swelling Index	Degree of matrix hydration and expansion

3.2 Post-Compression Evaluation of Floating Tablets

The post-compression evaluation is an important process to evaluate the mechanical strength, stability, and performance of floating tablets. To ensure formulation quality and therapeutic effectiveness, various parameters have been studied, such as hardness, friability, weight variation, drug content uniformity, floating lag time, and total floating time[15].The hardness of a tablet is of great importance for its structural integrity during packaging, transportation, and handling. Previous studies have indicated that optimized floating tablets have satisfactory hardness values and maintain buoyancy. Similarly, friability index values lower than the pharmacopoeial requirement of 1% indicate good mechanical resistance and robustness of the tablets[16].Weight uniformity and drug content uniformity are important quality attributes for ensuring uniform drug delivery. Studies reported in the literature are consistent and have shown that the preparation was within pharmacopoeial limits, indicating a homogenous distribution of the drug in the floating tablet matrices[1].

The two most important performance parameters of gastro-retentive systems are the floating lag time (FLT) and total floating time (TFT). Gas-generating agents, such as sodium bicarbonate, are added, resulting in the generation of carbon dioxide, and the tablets float in a short time[17]. Hydrophilic polymers, such as HPMC and Carbopol, form a gel barrier that traps the generated bubbles and helps maintain the tablets floating for a longer time. Numerous studies have demonstrated the effectiveness of floating systems in increasing gastric retention time, with floating times exceeding 12 h[18].

Table 3Common Post-Compression Parameters Reported for Floating Tablets

Parameter	Importance
Hardness	Mechanical strength of tablets
Friability	Resistance to abrasion and shock
Weight Variation	Uniformity of tablet weight
Drug Content	Uniformity of drug distribution
Floating Lag Time	Time required to initiate floating
Total Floating Time	Duration of tablet buoyancy
Swelling Index	Degree of matrix hydration and expansion

3.3 In Vitro Drug Release Behavior of Floating Tablets

In vitro dissolution is a commonly used technique to assess the dissolution behavior of floating tablet formulations. To study the sustained-release performance of various researchers have used simulated gastric fluid (0.1 N HCl, pH 1.2) for the study of Metformin Hydrochloride floating tablets[19].The type, concentration, and viscosity grade of the polymers used in the matrix system significantly affect the drug release profile. Hydrophilic polymers, such as hydroxypropyl methylcellulose (HPMC), absorb water when placed in dissolution media, creating a gel that controls the rate at which the drug diffuses. The superior swelling and gel-forming ability of carbopol has shown the ability to control drug release more effectively than some traditional matrix-forming polymers[20].It has been reported that the higher the concentration of polymer, the lower the rate of drug release, owing to the increase in the viscosity of the matrix and diffusion path length. As the gel barrier becomes more solid, the dissolution medium will not penetrate it as deeply, and the drug diffusion from the tablet matrix will be slowed down. Therefore, formulations with higher content of Carbopol or HPMC and Carbopol can usually give long duration of action up to 12–24 hours[21].

Table 4 Influence of Polymers on Drug Release Characteristics

Polymer	Major Function	Effect on Drug Release
HPMC K100M	Matrix former	Sustained release through gel formation
Carbopol 934P	Swelling polymer	Strong release retardation and prolonged buoyancy
Sodium Alginate	Gel-forming polymer	Improved matrix integrity
Xanthan Gum	Natural polymer	Controlled and extended release
Guar Gum	Hydrophilic polymer	Enhanced swelling and drug retardation

3.4 Drug Release Kinetics and Release Mechanisms

The kinetics of drug release can be useful in understanding the mechanisms of drug release from floating tablet matrices. Dissolution data reported in the literature have been used in several kinetic models, such as the zero-order, first-order, Higuchi, and Korsmeyer–Peppas models.These models, among others, are commonly seen in the floating tablet formulation of metformin hydrochloride, where the rate of drug release is found to vary with the remaining drug in the formulation matrix. In addition, the diffusion-controlled release process for hydrophilic polymer matrices is often modelled using Higuchi diffusion kinetics[22].The mechanism of release has been widely studied using the Korsmeyer–Peppas model. Non-Fickian (anomalous) diffusion was observed in many studies and indicates that the release of the drug is related to both diffusion and polymer relaxation/erosion mechanisms. These release rates are deemed beneficial in sustaining therapeutic drug levels and reducing plasma level swings[23].

Challenges

Although remarkable progress has been made in gastro-retentive drug delivery systems (GRDDS), the development and commercialization of floating drug delivery systems (FDDS) for Metformin Hydrochloride is still accompanied by many scientific, technological, physiological, and regulatory hurdles. Although floating tablets have proven to be highly promising for extending gastric retention, increasing bioavailability, and improving patient compliance, there are still some limitations to their clinical use. It is important to be aware of these challenges to develop more effective and patient-friendly gastro-retentive formulations[24].

A variety of Gastric Physiology

The most important difficulty with floating drug delivery systems is inter-patient gastric physiology and its variability. Gastric emptying time varies widely with age, sex, diet, disease state, emotional stress, and physical activity. Gastric motility plays a significant role in the formulation performance of floating systems and can therefore considerably influence the therapeutic efficacy of these systems[25]. The floating property of gastro-retentive systems is greatly affected by the presence or absence of food in the stomach. Migrating myoelectric complexes (MMC) can occur in the fasting state, leading to the rapid elimination of the dosage form from the stomach before the drug is released. In contrast, under fed conditions, gastric emptying is slower, which prolongs the time spent in the floating systems. This heterogeneity can cause unpredictable therapeutic effects and is one of the biggest hurdles to achieving predictable drug delivery. It is important to note that metformin hydrochloride requires a higher dose in people with high blood sugar levels[26].Metformin Hydrochloride is a formulation challenge given the high therapeutic dose. The dosage form of conventional oral dosage form usually contains an

amount of 500–1000 mg of the drug which makes it difficult to develop compact floating systems. The use of so much of a drug demands a substantial amount of matrix-forming polymers and buoyancy-enhancing agents, which means that bigger sizes of tablets are required[27].Larger tablet sizes can be difficult for patients and may cause swallowing problems, especially in children and elderly patients. In addition, it is difficult to formulate a product with sufficient buoyancy to handle a high drug load. The optimal size, floatability, and sustained drug release of tablets remain important research areas[28].

Maintaining Long-Term Buoyancy

The critical requirement for a floating drug delivery system is that it should be buoyant throughout the release period. However, long floating is sometimes difficult because of gastric changes and formulation characteristics. Most floating systems use gas-generating agents such as sodium bicarbonate and citric acid, which generate carbon dioxide. This mechanism is effective in the beginning of floating; however, a stable and robust polymeric gel matrix capable of entrapping the gas bubbles that are formed is necessary[29]. Low hydration of polymers, erosion, or excessive dissolution can result in the loss of buoyancy and early gastric emptying. Floating performance can be further affected by feed composition, fluid intake, and changes in stomach pH. Therefore, formulating products that remain buoyant in response to various physiological states is challenging. The selection of polymers and concentration optimization was optimized. The effectiveness of floating tablets depends mainly on the type, concentration, and combination of the polymers used[30]. Swelling control, matrix formation, and drug release are often regulated using hydrophilic polymers, including hydroxypropyl methylcellulose (HPMC), carbopol, sodium alginate, guar gum, and xanthan gum. However, it is not easy to choose the best concentration for a polymer. Too little of the polymer can lead to drug leaching too quickly, poor buoyancy, while too much of the polymer can lead to delayed drug release, larger tablet size, and production difficulties. Moreover, the swelling and gel formation properties of various polymers are different, making formulation optimization a lengthy and resource-intensive process. The challenge in floating tablet formulation is to obtain an optimum balance between buoyancy, swelling properties, mechanical strength, and controlled drug release[31].

Reproducibility issues and Scale-Up issues

Many floating formulations show good results in laboratory studies but face some difficulties in industrial-scale production. Scaling up tablet production can often cause problems with reproducibility of floating behavior, drug release kinetics, and tablet properties. The granulation process, compression force, drying temperature, particle size distribution, and equipment variability can all impact product quality. Variations in manufacturing parameters can produce variations in the structure of the matrix, which will impact buoyancy and dissolution[32].Achieving batch-to-batch consistency of formulations and guaranteeing the lowest possible drug delivery system cost are still significant challenges facing pharmaceutical companies aiming to commercialize floating drug delivery systems[33].

Drug Release Variability

One of the primary purposes of floating tablet formulation is to control drug release. However, multiple factors often make it difficult to obtain reproducible and predictable release profiles.

The release of the drug from a floating matrix will be affected by the polymer hydration, the swelling of the matrix, the pathways of the drug movement, the erosion rate and the environmental conditions. All these parameters can vary and cause changes in drug release characteristics. Metformin hydrochloride, which must maintain a constant level within the plasma, may not be as effective in controlling glucose and achieving treatment goals due to its inconsistent release profiles. Therefore, it is important to understand and manage the release mechanisms if a floating system is to be developed[34].

Stability Concerns

For successful commercialization of any pharmaceutical product, it is essential that it is stable over a long period of time. Floating tablets are frequently composed of moisture-sensitive polymers and effervescent agents that can react during storage. Moisture may cause premature reactions and loss of gas generation and buoyancy owing to the reaction between sodium bicarbonate and acidic components. Moreover, moisture uptake can also change the swelling properties of the polymer and impact drug release kinetics. Proper formulation stability is essential and includes appropriate packaging, storage conditions, and stability testing procedures. This increases the production costs and complexity[34].

Patient-to-Patient Variability

Physiological variability may have a tremendous impact on the function of gastro-retentive systems. Post-administration tablet behavior may be influenced by gastric pH, gastric volume, motility patterns, disease state, and co-administered drugs. Gastric retention times can be markedly different in patients with diabetic gastroparesis, gastrointestinal diseases, or impaired gastric motility. Thus, the therapeutic activity of floating tablets can vary significantly between patient groups. Patient-to-patient variability requires attention to obtain reliable clinical outcomes[35].

Poor limited In Vivo–In Vitro Correlation (IVIVC)

An important research challenge in gastro-retentive drug delivery is to establish a strong correlation between in vitro and in vivo performance. Laboratory dissolution and buoyancy studies can offer useful information; however,

many factors involved in human gastric physiology make it difficult to predict in vivo behavior. Vitamin D formulations with excellent in vitro floating properties may not necessarily have the same in vivo results in the gastrointestinal tract. However, the absence of strong IVIVC models makes formulation optimization, regulatory processes, and product development difficult[36].

Regulatory and Clinical Challenges.

The characterization, safety evaluation, stability studies, and clinical validation of novel gastro-retentive systems are extensive and require regulatory approval. To prove prolonged gastric retention and therapeutic efficacy, more advanced imaging and clinical studies may be required.These requirements add development costs and extend product development timelines. Moreover, there is little regulatory guidance that provides specific information for floating drug delivery systems, which adds to developers' uncertainty[37].

Economy, business, and trade issues.

Floating drug delivery systems have many therapeutic benefits; however, their commercialization is sometimes limited due to the complexity of manufacturing and production costs. The cost of development increases because of the use of advanced polymers, special excipients, and other quality control measures. Pharmaceutical companies face the challenge of innovating and creating new formulations that are also affordable. Meeting production costs while maintaining product quality is a significant issue for widespread adoption[38].

Conclusion

Floating drug delivery systems (FDDS) are promising gastro-retentive methods to improve the therapeutic efficacy of the drug, metformin hydrochloride, which is widely prescribed for type II diabetes mellitus. Literature reveals that floating tablets are effective in achieving the following: increased gastric residence time, increased bioavailability at the absorption site, sustained release, and decreased dosing frequency, which equates to improved patient compliance and therapeutic results. Buoyancy, matrix integrity, swelling behavior, and drug release kinetics are controlled by the careful selection and optimization of polymers, gas-generating agents, and other formulation components, which are crucial to the successful performance of these systems. Of the different polymers tested, hydrophilic matrix-forming agents, such as hydroxypropyl methylcellulose (HPMC) and carbopol, have shown great promise for the efficient formulation of floating systems. In particular, systems based on carbopol have often displayed better swelling characteristics, longer gastric retention, buoyancy, and better sustained-release properties, as a result of their ability to form strong gels. Many studies have proven that the polymer concentration and mixing are vital to control the drug release rate and floating properties for a long time.Although these promising results are obtained, there are a number of challenges that still need to be overcome to achieve complete clinical and commercial success for floating tablets of metformin hydrochloride. There are several key challenges in the formulation development process, including gastric physiology variations and differences in gastric emptying, high drug loading requirements, prolonged buoyancy maintenance, polymer optimization, stability issues, scale-up challenges, and regulatory issues. In addition, physiological variations in patients and the lack of correlation between in vitro and in vivo performance remain major problems for obtaining reproducible therapeutic response.

The literature shows that floating tablets are a good option for metformin hydrochloride for gastro-retentive action. These systems provide a promising approach for optimizing diabetes therapy by optimizing gastric retention, preventing drug release, and optimizing bioavailability. However, further studies are needed to address the existing formulation and clinical challenges to achieve the full therapeutic promise of these agents and to effectively move them from the laboratory to commercial clinical use. In the future, the development of more efficient, patient-friendly, and clinically effective oral drug delivery systems is expected to be greatly facilitated by the advancement of floating drug delivery technology.

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