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CONTROLLED DRUG RELEASE FROM ORAL DRUG DELIVERY SYSTEM

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ABSTRACT

The controlled release of the drug over a prolonged period of time is one of the fundamentals of controlled drug delivery. These dosage forms are necessary in order to sustain the drug concentration over a prolonged period of time. In the past, treating disease states required administering therapeutic agents in several dosages using a standard dosage form, such as tablets. Pharmaceutical polymers play a part in the development of such systems. This article gives a brief summary of the variety of designs for controlled release drug delivery systems in light of the current and future importance of this category of drug delivery system. The drug must be uniformly spread within a carrier system, either at the molecular level or as solid particles, for controlled or sustained drug delivery systems to work. The most common dosage is oral, such as matrix tablets. As a result, matrix tablets are discussed in this review. The release rate of drugs through oral drug delivery systems is affected by a number of things that can change the way matrix tablets are made. The development of this kind of formulation may benefit greatly from this information.

KEYWORDS: Controlled drug delivery, Sustained release drug delivery, Polymers, Matrix tablets

INTRODUCTION

Multiple daily doses of a therapeutic substance administered in a standard dosage form, such as tablets, have traditionally been used to treat disease states. Following administration, the drug enters the systemic circulation through a sequential process that includes: diffusion of the drug through the dosage form's matrix. The drug disintegrates in the gastrointestinal tract's aqueous fluid. The solution diffuses to the surrounding tissue, such as the villi of the small intestine, through the aqueous fluid of the digestive tract.

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The gastrointestinal tract wall is the route by which the drug is absorbed. The drug is deposited at the appropriate site of action after it reaches the systemic circulation. The drug is released from the dosage form in conventional oral drug delivery systems within a limited (specified) time window, allowing for subsequent absorption into the systemic circulation. In these conditions, the absorption stage regulates the onset and duration of a therapeutic agent's action. It is believed that increasing the drug's mass and rate of absorption will result in higher drug concentrations in the systemic circulation by ensuring higher drug concentrations at the site of action or absorption (Chien et al., 1992; Sweta et al., 2015; Agrawal et al., 1999; Turner et al., 2004; Carstensen et al., 1977; Sen et al., 2015; Garg et al., 2016).

CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

The drug is delivered by the controlled or sustained drug delivery systems in a consistent, controlled manner over a prolonged period of time (Sweta et al., 2017). The market offers a variety of dosage forms that deliver the drug to the body's desired location at the desired rate. Nanoparticles, microspheres, coating technology, and tablet formulation are examples of controlled or sustained drug delivery systems (Pandey et al., 2012; Shukla et al., 2012). These formulations can deliver the drug gradually or in a controlled way (Shukla et al., 2017, Shukla et al., 2016, Gour et al., 2016).

FACTORS INFLUENCING RELEASE OF DRUG FROM MATRIX TABLETS

An interest in designing and formulating dosage forms that control the subsequent release of drugs from the dosage form into the surrounding biological fluids has grown over the past forty years. As a result, this rating system effectively controls the therapeutic agent's pharmacological properties. Pharmaceutical polymers are used to make these kinds of systems. The following section gives a brief summary of the different types of controlled release drug delivery systems and the contribution/significance of polymers to their function in light of the current and future importance of this category of drug delivery system. The following sections are intended to give a general overview of controlled release drug delivery systems, and when appropriate, references to more specialized literature are included. This is to be emphasized to the reader. The drug must be uniformly spread within a carrier system, either at the molecular level or as solid particles, for controlled or sustained drug delivery systems to work. The most common dosage is oral, such as matrix tablets. As a result, matrix tablets are discussed in this review. Different parameters that affect the release rate of drugs through oral drug delivery systems have an impact on the formulations of matrix tablets.

Following are the factors which influence the release rate of drug from matrix tablets.

1. Effect of viscosity

A measure of a fluid's resistance to flow is called viscosity. When it comes to polymer solutions, the viscosity is dependent on the molecular weight of the polymer (Indian Academy of Sciences, 2010). Polymers can control this viscosity. The hydration of polymer chains by hydrogen bonding of oxygen atoms by their ether linkages, which causes them to extend and form relatively open random coils, is what gives polymer solutions their viscosity. The hydrated coils continue to form hydrogen bonds with additional water molecules held inside the coils (The Dow Chemical Company, 2000). In the beginning, these water molecules dissolve the drug and retain it. They then swell and form a network-like structure called a matrix, which reduces the drug's release because of higher viscosity through the hydrophilic matrices (Rahman et al., 2011).

Therefore, HPMC polymer with good viscosity grades is used in matrix systems to create sustained or oral controlled release drug delivery systems. The HPMC viscosities K100M, K15M, K4M, and K100LV are generally used. In contrast to the lower viscosity grade K100LV, the higher viscosity grade K100M controlled the release of the drug. A water-insoluble drug like diclofenac sodium releases from the HPMC K100M matrix over a longer period of time. It can avoid negative effects on the gastrointestinal tract. The higher viscosity grade of HPMC (K100M), according to numerous studies, can strengthen the gel layer and postpone the absorption of water into the dry matrix core. This causes the release of both water-soluble and water-insoluble active molecules to be delayed (Alderman, 1984).

2. Effect of pH

One of the most important things about GI fluids is their pH, which varies a lot along the digestive tract in people who are underfed and due to its environments (Charman et al., 1997). It affects how HPMC hydrophilic matrix systems behave. It may alter how a gel layer forms (Tritt-Goc et al., 2005). Additionally, the polymer's nonionic nature affects how a gel layer forms. HPMC polymers typically maintain their viscosities over a broad pH range of 3-11. Accordingly, drug release through the HPMC matrix surface will also be pH-dependent if the drug's solubility is pH-dependent (Asare-Addo et al., 2011). The transit time shows how long it takes for food to pass through each section of the GI tract. The release of theophylline from HPMC matrix tablets is influenced by transit time and pH values, which is a water-soluble drug. Higher drug release from low viscosity HPMC in acidic pH 1.2, which showed that the rate of drug release kept going down as pH went from acidic to alkaline.

Additionally, this research has shown that HPMC pH and molecular mass have an impact on the effects of hydration or swelling behavior (Tritt-Goc and Kowalczuk et. al., 2005). Using magnetic resonance imaging, the swelling characteristics of HPMC gell-like character are investigated at various time intervals (MRI). As the amount of time increases, a polymer's tendency to gel increases. It increases the polymer's surface area,

decreases the dry core, and demonstrates the developments of the gel layer over time. It was discovered that for low viscosity HPMC, the drug release is higher in acidic environments (i.e., the stomach), as the gel layer is thinner and allows for water penetration.

3. Effect of ionic strength

Ionic strength is an important factor of GI fluids. According to Asare-Addo et al. (2011) and Charman et al. (1997), it influences the rate of drug release from HPMC matrices. The food that a person consumes determines the GI fluid's ionic strength property.

Due to water and ion secretion, the ionic concentration in the jejunum is maintained steady. In fasted conditions, it is predicted to be around 0.14 M (Asare-Addo et al., 2011; Bonferoni et al., 1995; Lindhal et al., 1997). In general, the GI tract's ionic concentration strength in fed and fasted states ranges 0–0.4 M. (Johnson et al., 1993). According to a study by Asare-Addo et al. (2011), the ionic strength of the polymer increased the release rate of theophylline. The ionic concentration strengths, 0.2 M for low food content and 0.4 M for high food content, mimicked the potential effects of food. The findings showed that ionic concentration had a significant impact on the drug's release profile through the K100LV matrices. The K100M matrices, which produced a robust gel layer and had the lowest drug release rate, were found to be the best candidates for creating controlled release profiles that are less influenced by food.

4. Effect of cations

Researchers have developed modified polymers by combining alginate with various cations, including Al3+, Ca2+, Zn2+, and Mg2+ (Al-Musa et al., 1999; Nokhodchi and Tailor, 2004). These newly formed modified polymers are known as hydrogels because they create strong network-like bridges because of the presence of cations within a matrix (Braccini 1999; Ching et al., 2008). The egg-box concept can also be used to explain the hydrogel-like network. Using a two-dimensional approach, this egg-box model has described the bonding between alginate and divalent cations such as Ca2+ and Zn2+ (Grant et al. 1973). Divalent cations, such as aluminum ions, are found to have an additional positive charge per unit of surface, which facilitates cross-linking to a higher extent (Mohammadi, 2009). Microspheres, beads, and film coating have all been employed to control drug release from sustained-release formulations due to the formation of hydro-gels (Chan et al., 2006; Lee et al., 2005; Shukla et al., 2019). These cations are frequently utilized to produce cross-links in natural gum, and the resultant gum is then used to create matrix tablets. These naturally generated gums protect the matrix structure and prevent the matrix tablets from disintegrating too quickly (Ching et al., 2007). Because of this characteristic, derivative polymers can be used to develop controlled release agents. However, the amount of cation present in the polymer plays a

significant part in determining how fast or slowly the drug is released (Nokhodchi and Tailor 2004; Ching et al. 2007; Mohammadi et al. 2009).

5. Kinetics of drug release rate

The following equation, called the Higuchi equation, can be used to explain how drugs are released from hydrophilic matrices:

$M = k.t00.5$

Where M is the amount of drug delivered at time t, and k is a constant.

At first, Higuchi's equation only worked for planar matrix systems. Later, it was modified to take into account different geometric shapes, matrix properties, and porous structures (Lapidus and Lordi, 1966, 1968; Higuchi, 1963; Desai et al., 1965, 1966; Shukla et al., 2019). It is important to remember that it was the classical equation. Under the premise of a pseudo-steady state, it was derived. Real controlled release systems cannot be used with it (Peppas 1984; Kumar et al. 2019; Verma et al. 2020). The final kinetic equation demonstrates that if a system is primarily diffusion-controlled, a straight line will be observed on a plot of drug release with square root of time.

Although the mechanism of drug release from tablets with a hydrophilic matrix is complex, it is based on the drug diffusing through and eroding the outer hydrated polymer on the matrix's surface. In the case of a highly soluble drug, this may lead to an opening disintegrate release because the drug is on the surface of the matrix tablet. With time, the gel layer (rubbery state) swells and more water permeates the matrix film core, increasing the gel layer's thickness and creating a diffusion barrier that controls and slows down drug release (Rajabi-Siahboomi et al., 1996; Garg et al., 2018; Sahu et al., 2019). When defining the release kinetics of swellable matrices, the behavior of the gel layer thickness is critical. Water continues to penetrate through the gel layer of many other formulations and the matrix surface of tablets, releasing drugs through the eroding surface (Lee and Peppas 1987; Narasimhan and Peppas 1997; Kumar et al., 2018; Mishra et al., 2019). The gel layer's thickness, swelling, or rheological characteristics affect how quickly the medicine is released (Caramella et al., 1989). The gel layer's good thickness, swelling, and rheological characteristics demonstrated how important interactions between polymer-polymer and polymer-solvent are for controlling the gel network structure and erosion. Additionally, this sort of matrix' ability to control drug release can be greatly influenced by the gel's strength.

OTHERS FACTORS

There are other factors that influence the drug's rate of release via the matrix layer's surface. These factors are covered in further detail below, including:

1. Types of Formulation

The types of formulation, such as whether a drug is in the form of nanoparticles, microspheres, tablets, etc., are important elements that impact how fast a drug is released. If a dose formulation has higher surface area, the solubility of the drug will increase proportionately. As a result, the drug release rate is likewise influenced by these parameters (Shukla et al., 2020, Yadav et al., 2020).

2. Methods

For the manufacture of controlled or sustained release drugs, many techniques are used. Drug substances' solubility is affected by processes like matrix tablet formation. The direct or wet granulation methods can be used to develop the matrix formulation. The direct compression-based matrix tablets has a better swelling index than the wet granulation-based tablets. The tablets made from wet granulation did not have a good swelling index value, but they generated a more rigid network on the tablet's surface, which prevents water from penetrating. Accordingly, the technique of choice depends on the nature of drug candidates and polymers as well as the drug's target location (Jain et al., 2020; Shukla et al., 2020).

3. Nature of Polymers

The way a drug is released depends on the type of polymer. For example, if a drug is water-soluble, then water-insoluble polymers that deliver the drug into the intestine or pH-dependent polymers were used to make controlled or sustained release dosage forms.

4. Nature of Active Ingredient

The rate at which drug molecules are released is affected by the nature, type, and site of the delivery. The nature of the drug molecules is a major aspect in controlling the drug's release rate because the drugs may be either water-soluble or water-insoluble.

5. Dose of drug

The dosage formulation is impacted by the drug's dose and duration of action, which in turn impacts the drug's release (Shukla et al., 2017).

CONCLUSION

The most popular systems utilized by patients are oral controlled drug delivery dosage formulations. These dosage forms deliver the drug to the body and sustain the blood level of the drug for a prolonged period of time. In the current review article, we discuss all the

various elements that can affect a drug's rate of release, including formulation type, polymer type, drug type, viscosity of polymer, pH, ionic strength, cross-linking with cations, and drug target site. These characteristics must be taken into consideration as the perfect controlled release formulation is developed, and dose dumping effects must be eliminated. The release kinetics of several oral dose formulations using natural, synthetic, and modified polymers was investigated. Therefore, a drug formulation might be designed to deliver a sustained, controlled type of effect based on this behavior. The prospective controlled and sustained release oral dosage formulation was therefore found to require consideration of the variables that influence the drug's release rate. Additionally, bear in mind the aforementioned idea before designing or developing a medicine with an oral controlled release.

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