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A Review on Sustained Release Formulation with Its Polymer and Evaluation of Sustained Release Tablets

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ABSTRACT

The fundamentals of sustained release formulation design and its various varieties are covered in this article. For pharmaceutical technologists, creating oral sustained release matrix tablets with a consistent release rate has always been difficult. By optimizing the bio-pharmaceutics, pharmacokinetics, and pharmacodynamics properties of drugs in a way that minimizes dosing frequency to the point where a single daily dose is adequate for penetration, polymer swelling, drug dissolution, drug diffusion, and matrix erosion, oral sustained release (SR) products offer an advantage over traditional dosage forms. Sustained release matrix tablets have been developed for medications that are very soluble in water, such as ranitidine and diltiazem. Drug delivery systems that are intended to accomplish or prolong therapeutic effect by continuously releasing medication over an extended period of time following administration of a single dose are referred to as sustained release, prolonged release, modified release, extended release, or depot formulations. These dosage forms are appealing for a number of reasons: they increase the drug product's bioavailability, decrease the frequency of administration to extend the duration of effective blood levels, lessen peak trough concentration fluctuations and side effects, and potentially improve the drug's specific distribution.

Key words: polymers, controlled drug delivery, matrix system.

INTRODUCTION

In order to successfully develop an oral pharmaceutical dosage form, all pharmaceutical products formulated for systemic delivery via the oral route of administration must be developed within the intrinsic characteristics of GI physiology, pharmacokinetics, pharmacodynamics, and formulation design, regardless of the mode of delivery (immediate, sustained, or controlled release) and the design of dosage forms (either solid dispersion or liquid).The pharmaceutical industry has long recognized the benefits of giving a single dose of a medication that is given gradually rather than multiple doses. Maintaining a nearly constant or consistent blood level of a medication frequently results in improved patient compliance and increased clinical efficacy for the intended use of the medication. The development of sustained release or controlled release drug delivery systems has received more attention due to the growing complexity and cost associated with marketing novel pharmacological entities. For sustained release, matrix systems are frequently utilized. The drug's dissolved or dispersed release is prolonged and regulated by the release system. Actually, a well-mixed combination of one or more medications with a gelling agent, such as hydrophilic polymers, is called a matrix. Reducing a drug's rate of release from the dosage form can lower its absorption rate, which is one of the intriguing findings of pharmaceutical research. Sustained action, delayed action, protracted action, depot, respiratory, retarded release, and timed release medications are the names given to these products. The development of sustained or controlled drug delivery systems has received more attention over the past 30 years as the cost and complexity of selling novel entities have increased along with the therapeutic benefits of controlled drug administration. Since sustained release technology is a relatively new discipline, research in this area has been quite fruitful and has yielded numerous

discoveries. Achieving a steady state blood level that is both therapeutically beneficial and non-toxic for a long time is the fundamental objective of many medications. A key component in achieving this objective is the formulation of an appropriate dosage form. Drug delivery systems that are intended to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose are referred to by terms such as sustained release, sustained action, prolonged action, controlled release, extended action, timed release, and depot dosage form. Depending on how long the formulation stays in the GIT, an oral sustained released dose form can have an impact for a few hours. Therapeutic substances must be administered on a regular basis as part of conventional pharmacological therapy. These substances are designed to have the highest levels of bioavailability, stability, and activity. Conventional drug administration techniques work well for the majority of medications, although some have limited therapeutic ranges and are toxic or unstable. Additionally, several medications have issues with solubility. In these situations, it is preferable to provide the therapeutic medication continuously in order to maintain stable plasma levels.

CLASSIFICATION OF MATRIX TABLETS

(a) On the Basis of Retardant Material Used: Matrix tablets can be divided in to 5 types.

1. Hydrophobic Matrices (Plastic matrices)

In 1959, the idea of employing inert or hydrophobic materials as matrix materials was first presented. The medicine is combined with an inert or hydrophobic polymer and crushed into a tablet in order to provide prolonged release from an oral dosage form. A network of channels between compressed polymer particles allows the dissolving medication to spread, resulting in sustained release. Polyethylene, polyvinyl chloride, ethyl cellulose, acrylate polymers, and their copolymers are a few materials that have been employed as inert or hydrophobic matrices. Liquid penetration into the matrix is the rate-controlling stage in these formulations. Diffusion is one potential medication release mechanism in these kinds of tablets. When water and gastrointestinal fluid are present, certain kinds of matrix tablets become inert.

2. Lipid Matrices

Lipid waxes and related components are used to produce these matrices. Drug release from these matrices happens via erosion and pore diffusion. Therefore, the nature of the digestive fluid affects release characteristics more than the completely insoluble polymer matrix. For several prolonged release formulations, carnauba wax has been used as a retardant base in conjunction with stearyl alcohol or stearic acid.

3. Hydrophilic Matrices

Oral controlled drug delivery makes extensive use of hydrophilic polymer matrix systems due to their widespread regulatory approval, cost-effectiveness, and flexibility in achieving a desired drug release profile. In the realm of controlled release, the use of hydrophilic polymers with high gelling capabilities as base excipients in the formulation of medications 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 called an infected matrix. We refer to these systems as swellable controlled release systems. Three major categories comprise the polymers utilized in the creation of hydrophilic matrices:

A. Cellulose derivatives: Methylcellulose 400 and 4000 cPs, sodium carboxymethylcellulose, hydroxyethyl cellulose, and hydroxypropylmethylcellulose (HPMC) 25, 100, 4000, and 15000 cPs.

B. Non cellulose natural or semi synthetic polymers: Agar-agar, carob gum, alginates, molasses, mannose and galactose polysaccharides, chitosan, and modified starches.

Polymers of acrylic acid: Carbopol-934, the most used variety.

4. Biodegradable Matrices

These are made up of polymers with unstable backbone linkage that are made up of monomers connected to one another by functional groups. Enzymes produced by nearby live cells or nonenzymetic processes break them down biologically into oligomers and monomers that can be digested or eliminated. Natural polymers like proteins and polysaccharides, modified natural polymers, and synthetic polymers like aliphatic polyesters and poly anhydrides are a few examples.

5. Mineral Matrices

These are made up of polymers derived from different seaweed species. Alginic acid, for instance, is a hydrophilic carbohydrate that is extracted from brown seaweed species (Phaephyceae) using diluted alkali.

- On the Basis of Porosity of Matrix:

Additionally, matrix systems may be categorized based on their porosity, allowing for the identification of macro porous, micro porous, and nonporous systems:

1. Macro porous Systems: In these systems, the medication diffuses via matrix holes that range in size from 0.1 to 1 μm. The size of this hole is greater than that of diffusant molecules.

2. Micro porous System: In this kind of system, diffusion basically happens through pores. Pore sizes in microporous systems vary from 50 to 200 A°, which is somewhat bigger than the size of diffusant molecules.

3. Non-porous System: The molecules in non-porous systems diffuse across the network meshes because they lack pores. In this instance, there is no pore phase—just the polymeric phase.

POLYMERS USED IN THE MATRIX

Both hydrophilic and hydrophobic polymers are most frequently utilized in matrix system preparation.

(A) Hydrophilic Polymers: Xanthan gum, sodium alginate, hydroxyl ethyl cellulose (HEC), hydroxyl propyl cellulose (HPC), hydroxyl propyl methyl cellulose (HPMC), and cross-linked homopolymers and co-polymers of acrylic acid.

(B) Hydrophobic Polymers: In their formulation, waxes and water-insoluble polymers are often used.

(C) Waxes: Low molecular weight polyethylene, carnauba wax, beeswax, candelilla wax, microcrystalline wax, ozokerite wax, and paraffin wax.

(D) Insoluble polymers latex dispersion of meth acrylic ester copolymers, ethyl cellulose, cellulose acetate butyrate, cellulose acetate propionate, and ammoniomethacrylate copolymers (Eudragit RL100, PO, RS100, PO).

EVALUATION OF SUSTAINED RELEASE TABLETS

Assuring a product's strength, safety, stability, and dependability through in-vitro and in vivo studies and correlation between the two is necessary prior to selling a sustained release product. The parameters and methods for assessing sustained release formulations have been covered by a number of writers.

1. In-Vitro Methods

These are: - a. Beaker method b. Rotating disc method c. Rotating Bottle method d. Rotating Basket method e. Stationary Basket Method f. Oscillating tube method g. Dialysis method h. USP dissolution method.

2. In–Vivo Methods

It becomes vital to do in-vivo evaluation and establish in-vitro in-vivo correlation after the suitable in-vitro profile is attained.

The various in-vivo evaluation methods are: -a. Clinical response b. Blood level data c. Urinary excretion studies d. Nutritional studies. e. Toxicity studies f. Radioactive tracer techniques

3. Stability Studies: To guarantee the strength, safety, identity, quality, purity, and in-vitro in-vivo release rates that they claim to have at the time of use, the medicine and its dosage form must have sufficient stability data. A sustained release product should release a fixed quantity of the medication at regular times, which shouldn't alter while being stored. The continuous release product would be meaningless if there was a significant departure from the proper release. Temperature and humidity are examples of atmospheric or accelerated variables that can change the sustained release product's in-vitro and in-vivo release rates. A sustained release product's stability programs involve storage at both nominal and accelerated settings, such as temperature and humidity, to make sure the product will survive these circumstances.

4. In vitro- In vivo Correlations:

It goes without saying that developing sustained release delivery systems requires a strong in-vitro-in-vivo connection. The biopharmaceutics and pharmacokinetics of the therapeutic agent in the body following its release from the drug delivery system, as well as the pharmacodynamics of the therapeutic agent at the site of drug action, must all be taken into account in order to make a significant in vitro in vivo correlation. By concurrently evaluating a possible drug delivery system in vitro and in vivo to examine and contrast the mechanism and rate profiles of sustained drug release, a straightforward in vitro-in vitro link may be formed. The in-vitro in-vivo correlation factor is determined once the in-vivo drug release mechanism is demonstrated to be in excellent agreement with that found in the in-vitro drug release investigations. The factor may be expressed as follows for a medication delivery strategy that uses capsules:

(Q/t) In-vivo

Q= (Q/t) In-vitro

Where,

Q/t = Rate of release

‘Q’ values are dependent profiles of drug delivery systems. upon the sites of administration and environmental conditions to which the animals are exposed during treatment (study).

The above relationship can be used for optimization of sustained release Levy has classified In-vivo-In-vitro correlation in to:

a] Pharmacological correlations based on clinical observations;

b] Semi-quantitative correlations based on blood levels or urinary excretion data;

c] Quantitative correlation arising from absorption kinetics. While most of the published correlations are of semi-quantitative nature, the most valuable are those based on absorption kinetics.

5. Bioavailability Testing: The velocity and degree of unaltered medication absorption from the site of application to the general circulation is commonly referred to as bioavailability. The phrase "bioavailability" refers to a particular drug moiety, often an active therapeutic agent, which might be the medication itself or, in the case of a prodrug, a metabolite. On the other hand, "absorption" frequently refers to the net movement of drug-related mass into the body from the application site. Therefore, when poor bioavailability results from imperfect absorption, a substance may be fully absorbed but only partially accessible. To enhance the drug's absorption properties and, consequently, its bioavailability, pharmaceutical dosage form modification may be necessary. Bioavailability studies typically compare a tested drug product's single dosage in healthy people who are fasting. It is preferable to use a crossover design, where each subject receives the product and reference material on separate days. For multiple dosage trials, guidelines for clinical testing have been released. Validating the sole importance of sustained release claims may need a correlation between bioavailability and pharmacological activity or clinical proof of therapeutic benefit. Multiple dose studies are necessary to determine the ideal dosing schedule, although single dose studies are typically adequate to demonstrate the validity of sustained release dosage form design.They are also necessary when there may be variations in the rate of absorption but not its magnitude. when the observed blood levels following a single dosage are too low to be precisely quantified, or when there is significant subject-to-subject variance. To achieve steady state blood levels, a sufficient number of doses must be given. An detailed research of sustained release theophylline products revealed that, for instance, encapsulated versions demonstrated improved regulation of blood levels within the required range due to reduced peaking over successive dosage.

CONCLUSION

In addition to enhancing the patient's compatibility, sustained-release formulations assist increase the dose's efficiency. Matrix-forming polymers may be effectively employed to create Matrix tablets, which release medication in a regulated way. Release kinetics may be readily adjusted to meet delivery requirements thanks to preparatory methods. The relevance of these specific excipients in pharmaceutical applications is confirmed by the matrix-forming polymers' adaptability for different drug delivery systems production. For several oral delivery issues, such as varying medication plasma levels, limited bioavailability, more frequent dosage administration, etc., they are the preferred option. Therefore, matrix tablets can solve the aforementioned issues with traditional oral medication distribution.

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