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A Review on Formulation Development of Bilayer Floating Tablet

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ABSTRACT
In the recent past, controlled release concept and technology have received increasing attention in the face of growing awareness to toxicity and ineffectiveness of drugs when administered or applied by conventional methods. Thus drugs applied in the form of tablets, capsules, injectables and ointments etc., usually produce wide range of fluctuations in drug concentration in the blood stream and tissues with consequent undesirable toxicity and poor efficiency. This factor as well such as repetitive dosing and unpredictable absorption led to the concept of controlled drug delivery systems or therapeutic systems[3]. A dosage form that one or more drugs continuously released in a predetermined pattern for a fixed period of time, either systematically or to a specified target organ is a controlled drug delivery system. The event of drug delivery system brings rate controlled delivery with fewer side effects, increased efficacy and constant delivery. The primary objective of controlled drug delivery systems is to ensure safety of drugs as well as patient compliance

KEYWORDS: Sustained Drug Delivery , Bi-layer Tablet, Hydrophilic polymer

I. INTRODUCTION:

There has been 60 years of research and development experience in the sustained drug release area since the patent, and a number of strategies have been developed to prolong drug level in the body. With many drugs, the basic goal of therapy is to achieve a steady-state blood or tissue level that therapeutically effective and non-toxic for an extended period of time.

The goal of any drug delivery systems is to provide a therapeutic amount of drug to the proper site in the body to achieve promptly and then maintain the desired drug concentration. Two aspects are most important to drug delivery, namely spatial placement and temporal delivery of a drug[4]. Spatial placement related to targeting drug to a specific organ or tissue. While temporal delivery refers to controlling the rate of drug delivery to the target tissue.

1.1 REQUIREMENTS FOR SUSTAINED DRUG RELEASE[4]

Design of sustained release products is normally a very difficult task because of interplay of the physical-chemical-biological properties of the drug, the patient disease state and technological limitations in fabrication of the final dosage form. Depending upon the drug, disease state, route of administration, but before a final decision is made to proceed with the dosage form; all these factors must be considered.

1.1(a) ADVANTAGES OF SUSTAINED RELEASE DOSAGE FORM[5]

- Frequency of drug administration is reduced.
- The Patient compliance can be improved, and drug administration can be made more convenient.
- Blood level oscillation characteristic of multiple dosing of conventional dosage forms is reduced, because a more even blood level is maintained.
- Implicit in the design of sustained release forms, is that the amount of drugadministered can be reduced, thus maximizing availability with a minimum dose.
- The safety margin of high-potency drugs can be increased, and the incidence of both local and systemic adverse side effects can be reduced in sensitive patients.

1.2(b) DISADVANTAGES

- Administration of sustained release medication does not permit the prompt termination of therapy.
- The physician has less flexibility in adjusting dosage regimens. This is fixed by the dosage form regimen.

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- Sustained release forms are designed for the normal basis of average drug biologic half-lives. Consequently, disease states that alter drug disposition, significant patient variation, so forth are not accommodated.
- Economically more costly processes and equipment are involved in manufacturing many sustained release forms

1.2. HYDROPHILIC POLYMER MATRIX SYSTEM (HPMS)

Hydrophilic Polymer Matrix System (HPMS) are widely used in oral controlled drug delivery because they make it easier to a desirable drug-release profile, as they are cost effective and have abroad US FDA acceptance. It consists of hydrophilic polymer, drug and other excipients distributed throughout the matrix[6]. This dynamic system is dependent on polymer wetting, hydration and dissolution for controlled release of drug. At the same time, other soluble excipients (or) drug substance will also wet, dissolve and diffuse out of the matrix, whereas insoluble excipients (or) drug substances will be held in place until the surrounding polymer, excipients (or) drug complex erodes (or) dissolves away.

Matrix controlled release tablet are relatively simple system that are more forgiving of variations in ingredients, production methods and end-use conditions when compared to coated controlled release tablets of other systems. This results in more uniform release profiles with a high resistance to drug dumping. Hydrophilic matrix systems are relatively easy to formulate with existing conventional equipments and processing method[5]. One goal of this study was to develop uncoated HPMC matrix tablet by wet granulation process, ev

1.2(a) ADVANTAGES OF HYDROPHILIC MATRIX SYSTEM

- Generally regarded as a safe excipient.
- Simple concept.
- Erodable – reducing ghost matrices.
- Easy to manufacture.
- Possible to obtain different release

1.2(b) DISADVANTAGES

- Need optimal rate controlling polymers.
- Scale of problems.
- Release of drug depends upon penetration of water and diffusion of drugs throughhydrated matrix.

If outer matrix layer erodes, complication in drug release profile takes place. These matrix tablets are resistant to dose dumping due to simple nature of formulation by hydrophilic colloid matrices are being robust they are unaffected by variation in ingredients. An important factor for modified release is the ability of hydrophilic polymers to readily hydrate and form a gel.
Aluating the relationship and influence of excipients.

1.3. MECHANISM OF DRUG RELEASE FROM HYDROPHILIC MATRIX SYSTEM[8]

On exposure to aqueous fluid, hydrophilic matrices take up water, and polymer starts hydrating to form a gel layer. Drug release is controlled by diffusions barriers / or by surface erosion. An initial burst of soluble drug may occur due to surface leaching when a matrix containing a swell able glassy polymer comes in contact with an aqueous medium, there is an abrupt change from a glassy to a rubbery state which is associated with swelling process with time, water infiltrator deep into the case increasing the thickness by the gel layer.

Concomitantly the outer layer becomes fully hydrated and states dissolving or eroding. When water reaches the center of the system and the concentration of drug fells below the solubility value, the release rate of drug begins to reduce. At the same time, an increase in thickness of the barrier layer with time increases the diffusion path length, reducing the rate of drug release. Drug release kinetic associated with these gel – layer dynamic, range initially from Fickian to anomalous (Non – Fickian) and subsequently from quasi – Constant(near Zero order) to constant. In general, two major factors control the drug release from swelling controlled matrix system. They include: The rate of aqueous medium infiltration into the matrix, followed by a Relaxation process (i.e. hydration gelation swelling).

As a result of these simultaneous processes, two front are evident, a swelling front, where the polymer get hydrated, and an eroding front. The distance between these two fronts are called diffusion layer thickness. Diffusion layer thickness depends on the selective rate at which the swelling and eroding fronts move in relation to each other. If the polymer gets slowly, solvent can penetrate deep into the glassy matrix the dissolving the drug; there for gel layer thickness and it

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stability are council in controlling drug release.

Swelling of HPMC matrix tablet was higher for higher a molecular weight. They attributed this to the large hydrodynamic volume occupied by higher molecular weight chain when hydrated. As the polymer chain becomes more hydrated and the gel becomes more dilute, the disentanglement concentration may be reached that is, the critical polymer concentration below which the polymer chain disentangles and detached from gelled matrix.

The mechanism by which drug release controlled in matrix tablet is dependent on many variables, however the main principle is that the water-soluble polymer present throughout the tablet hydrates on the outer tablet surface to form a gel lager. Throughout the life of the ingested tablet, the rate of drug release is deferment by diffusion (if soluble) through the gel and by the rate of tablet erosion (if insoluble).

1.4. BILAYER TABLET[9, 10]

A type of multilayered tablet in which instead of single tablet two layers were formulated by which two incompatible drugs can also be combined together in same formulation.

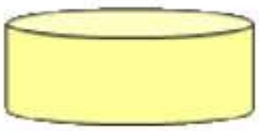

Fig.Bilayer Tablet

1.4 (a)ADVANTAGE[11]

- A new platform technology for decreasing the chemical incompatibility.
- Release of one drug as immediate and another drug as sustained.
- Two layers are visible, so unbonded tablets can be easily detected.
- Less coating material is required.

1.4 (b) THE GOAL TO DESIGNING BILAYER TABLETS:

- Controlling the delivery rate of either single or two different API'S.
- To separate incompatible API's with each other, to control the release of one layer by utilizing the functional property of the other layer (such as osmotic property).
- For the administration of fixed dose combinations of drugs, Prolong the drug product life cycle, buccal muco adhesive delivery systems, manufacture novel drug delivery systems such as chewing device and floating tablets for gastro-retentive drug delivery systems.
- To adapt the total surface area available for layer either by sandwiching with one or two inactive layers in order to achieve swell able / erodible barriers for controlled release.
- Bi-layer tablet is suitable for sequential release of two drugs in combination, separate two incompatible substances and also for sustained release tablet in which one layer is immediate release as initial dose and second layer is maintenance dose. In which the one layer is formulated to obtain immediate release of the drug, with the aim of reaching a high serum concentration in a short period of time. The second layer is a controlled release, which is designed to maintain an effective plasma level for a prolonged period of time. The pharmacokinetic advantage relies on the fact that drug release from fast releasing layer leads to a sudden rise in the blood concentration. However, the blood level is maintained at steady state as the drug is released from the sustaining layer.

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