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Modified release dosage form and drug delivery

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ABSTRACT

In past decade great interest got generated on replacing conventional administration of drugs by delivery system which would release effective quantities form a protected supply at a controlled rate over a long period of time. Ideally a drug to provide desired therapeutic action should arrive rapidly at the site of the action (receptor) in optimum concentration, remaining there for desired time, spare other site and get removed from the site, one of the most recent and interesting result of pharmaceutical research is the fact that absorption rate of release from the dosage form . The product so formulated are designed as sustained action, sustained release, prolonged action, depot, retard action, delayed action, that products in most case are similar in appearance.

Keywords: Sustained release; prolonged release.

INTRODUCTION

Drug products designed to reduce the frequency of dosing by modifying the rate of drug absorption have been available for many years. Early modified release products were often intramuscular/subcutaneous injection of suspensions of insoluble drug complexes, eg. Procaine penicillin, protamine zinc insulin, insulin zinc suspension or injections of the drug in oil, eg. Fluphenazine decanoate. Advance in technology have resulted in novel modified release dosage form. In contrast to conventional (immediate release) forms, modified release products provide either delayed release or extended release of drug.

Extended release products are designed to release their medication in a controlled manner, at a predetermined rate, duration, and location to achieve and maintain optimum therapeutic blood levels of drug .[1,2]

Terminology:

Drug products that provide extended release first appeared as a major new class of dosage form in the late 1940's and early 1950s. over the years, many terms (and abbreviations), such as sustained release(SR), sustained action (SA), prolonged action (PA), controlled release (CD), extended release (ER), timed release (TR), and long acting (LA), have been used by manufactures to describe product types and features. Although these terms often have been used interchangeably, individual products bearing these descriptions may differ in design an performance and may differ in design and performance and must be examined individually to as certain their respective features.

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Sustained release

In case of sustained release (SR) dosage forms the release of the active agent, although, is lower than in the conventional formulations,
however, it is still substantially affected by the external environments into which it is going to be released.

Controlled release

Controlled release (CR) systems provide drug release in an amount sufficient to maintain the therapeutic drug level over extended period of time, with the release profiles of predominantly controlled by the special technological construction and design of the system itself. The release of the active constituent is therefore, ideally independent of exterior factors.

Extended release

Extended release formulation is a controlled release formulation designed to produce even and consistent release of active ingredient. Extended release (ER) dosage forms are those which due to special technology of preparation provided, soon after a single dose administration, therapeutic drug levels maintained for 8-12 hours.

Prolong action

Prolong or long action products are dosage forms containing chemically modified therapeutic substances in order to prolong biological half live (Lee and Robinson, 1987). [1, 3, 4, 5, 6, 7, 8.]

Classification:

Modified Release dosage form may be classified as

A .Delayed release

B. Extended release

B.1: Sustained release

B.2: Controlled release

C. Site-specific and receptor targeting.[4.]

Advantages of modified release dosage form:

1) Improved therapy:

a) Sustained plasma drug concentration level.

The dosage form provides uniform drug availability unlike peak and valley pattern obtained by intermittent administration.

b) Attenuation of adverse effects.

The incidence and intensity of undesirable side effects caused by excessively high peak drug concentration resulting from the administration of conventional dosage forms is reduced.

c) It is seldom that a dose is missed because of non-compliance by the patient.

2) Patient Convenience/improved patient compliance:

Frequency of administration is reduced and thus disturbance to the patient is less particularly at night (resting time).

3) Economy:

Economy may also be affected due to decreased cost of nursing time for administration of drug.

4) Reduce amount of drug administration

5) Maximizing availability with a minimum dose.

6) Control of drug absorption; high peak level peaks that may be observed after administration of high availability drug can be reduced.

7) Safety margin of high potency drugs can be increased.

8) Increased reliability of therapy. [9 – 13.]

Disadvantages:

However, sustained release products are not altogether free from disadvantages some of which are as follows:

1) Dose Dumping

Dose dumping is a phenomenon where by relatively large doge in a controlled release formulation is rapidly release, introducing potential toxic quantities of the drug into the systemic circulation .Dose dumping can lead to facilities incase of potent drug, which have a narrow therapeutic index. e.g. Phenobarbital.

2) Less flexibility in acute dose adjustment:

In convenient dosage form, dose adjustments are much simpler e.g. tablet can be divided into two fractions. In case of controlled / sustained release dosage forms, this appears to be much more complicated. Controlled release property may get lost, if dosage form is fractured.

3) Poor in vitro – in vivo correlation:

In controlled release dosage form, the rate of drug release is deliberately reduced to achieve drug release possibly over a large region of gastrointestinal tract. Here the so called "Absorption Window" become important and may give rise to unsatisfactory drug absorption in vivo despite excellent in vitro release characteristics.

4) Patient variation:

The time period require for absorption of drug release from the dosage form may vary among individuals. Co-administration of other drugs, presence or absence of food and residence time in GIT is different among patients. This also gives rise to variation in clinical response among the patient.

5) In case of accidental failure of the product effective antidote may be difficult to employ.

6) Sustained Release dosage forms are some time costlier because of the technology involved in producing the formulation.

7) Sustained Release medication should not be used with person known to have impaired or erratic gastrointestinal absorption or kidney troubles.

8) Drugs having long biological half life are not suitable for presentation in Sustained Release form, eg. digitoxin.

9) There is little control in hands of the physician so far as dose variation is concerned.

10) Problem incase of elderly people. [2, 9 - 13.]

CONCLUSION:

The conventional drug delivery systems have been gradually replaced from last few years by various modified release drug delivery systems based on high technology. Targeting a tissue is known to be a complex process consisting of multiple steps in penetration such as diffusion and partitioning. The modified release drug delivery system addresses the initial step of this complex process, but the path for transport of drug molecules from the delivery system to the tissue remains largely uncontrolled. The ultimate goal is to get optimal treatment with maximal safety. This can be reasonably accomplished by development of models that is constructed from a non immunogenic and biodegradable polymer backbone attached with exact functional group. This drug delivery system is only in the conceptual stage. Its full construction is a challenging task for the biomedical and pharmaceutical sciences.[14]

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