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Review Article

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A REVIEW ON SPANSULES: A NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT

It is suggested that the spansules are one of the best drug delivery, in this form of pharmaceutical formulation the multiple drug contents are being microencapsulated and filled in a capsule shell leading to efficient drug delivery. It has a slow dissolving rates and follows zero order kinetics so provide constant plasma drug concentration followed by controlled release of drug.

KEYWORDS: Granules formation, microencapsulation, controlled release and sustained release.

INTRODUCTION

The oral route is considered as the most common and convenient route for controlled delivery of drugs due to following reasons.

- 1. Ease of administration.
- 2. Patient compliance.
- 3. Multidrug therapy in single dose.

Spansules is a capsule which when swallowed releases one or more medicinal drugs over a set period. Spansules are defined as capsules containing medicines (in form of granules), coated with materials having slow dissolving rates so that the medicament is delivered at different specific time.

In this formulation the drug particles are coated or encapsulated by one of the several microencapsulation techniques with slowly dissolving materials like waxes, polyethylene glycol PEGs cellulose etc. The resulting pellets or coated granules are filled in hard gelatin capsules popularly called as spansules. This are mainly transparent in appearance we can see easily colour granules in it. This system can produce a rapid increase in plasma concentration of drugs such as analgesic, anti-inflammatory, anti hypertensive, etc. That are requested

promptly exercise the therapeutic effect followed by a prolonged release phase to avoid repeated administration.^[1] The dissolution rate of coat depends upon the solubility and thickness of coating (1-200 microns).^[2] The thickness of coating allows the slowly dissolving of a medicament over a long period of time.

A spansules contains hundreds of coloured pellets or granules divided into 3 to 4 groups which differ in their thickness of time-delay coating. These pellets or granules provide loading dose and release drugs at 2 or 3 hours, 4 or 6 hours, and 6 or 9 hours. The drug release depends on permeation of moisture to the coated particles (core) resulting in the swelling, ruptures the coating, thus followed by releasing drug.^[3]

Spansules comes under dissolution controlled release systems, reservoir type. Generally, hydrophilic polymers or hydrophobic polymer either single or combinations are used for the coating of granules. Examples include gelatin, cellulose derivative (ethyl cellulose, methyl cellulose, HPMC, etc.), polyvinyl alcohol, cellulose acetate phthalate.

Terminology

Controlled drug delivery or modified release delivery systems may be defined as follows:-

Controlled release formulation

The controlled release system is to deliver a constant supply of the active ingredient, usually at a zero-order rate, by continuously releasing, for a certain period of time, an amount of the drug equivalent to the eliminated by the body. An ideal Controlled drug delivery system is the one, which delivers the drugs at a predetermined rate, locally or systematically, for a specific period of time.

Repeat action preparations

A dose of the drug initially is released immediately after administration, which is usually equivalent to a single dose of the conventional drug formulation. After a certain period of time, a second single dose is released. In some preparation, a third single dose is released after a certain time has elapsed, following the second dose.

Extended-Release formulation

Extended-Release formulations are usually designed to reduce dose frequency and maintain relatively constant or flat plasma drug concentration. This helps avoid the side effects associated with high concentration.

Delayed release preparations

The drug is released at a later time after administration. The delayed action is achieved by the incorporation of a special coat, such as enteric coating, or other time barriers such as the formaldehyde treatment of soft and hard gelatin capsules. The purposes of such preparations are to prevent side effects related to the drug presence in the stomach, protect the drug from degradation in the highly acidic pH of the gastric fluid.

Site specific targeting

These systems refer to targeting of a drug directly to a certain biological location. In this case the target is adjacent to or in the diseased organ or tissue.

Receptor targeting

These systems refer to targeting of a drug directly to a certain biological location. In this case the target is the particular receptor for a drug with in organ or tissue. Site specific targeting and receptor targeting systems satisfy the spatial aspect of drug delivery and are also considered to be controlled drug delivery systems.

Advantages of Controlled Release Drug Delivery System

- 1. Therapeutic advantage.
- 2. Reduction in adverse side effects and improvement in tolerability.
- 3. Patient comfort and compliance.
- 4. Reduction in Health care cost.

Disadvantages

- 1. Dose dumping.
- 2. Less flexibility in accurate dose adjustment.
- 3. Poor In-vitro In-vivo correlation.
- 4. Increased potential for first pass clearance.

Sustained release (S.R) / Controlled release (C.R) products provide an advantage over conventional dosage forms by optimizing bio-pharmaceutics, pharmacokinetic and pharmacodynamics properties of drugs in such a way that it reduces dosing frequency to an extent that once daily dose is sufficient for therapeutic management through uniform plasma concentration providing maximum utility of drug with reduction in local and systemic side effects and cure or control condition in shortest possible time by smallest quantity of drug to

586

assure greater patient compliance. This review describes the various factors influencing the design and performance of sustained/controlled release products along with suitable illustrations. The release models with major application and best describing drug release phenomena are, in general, the Higuchi model, zero order model, first order model and Korsemeyer-Peppas model. Further, it can be added that the physicochemical properties of the drug as well as polymer and the drug to polymer ratio govern the release of drug from the formulation and thus, modify the release kinetics accordingly.

Classification of oral CDDS

1. Continuous Release System

- a. Dissolution controlled release systems
- b. Diffusion controlled release systems
- c. Dissolution and diffusion controlled release systems
- d. Ion exchange resin drug complexes
- e. pH dependent formulations
- f. Osmotic pressure controlled system
- g. Hydrodynamic pressure controlled systems
- h. Slow dissolving salts and complexes

2. Delayed Transit and continuous release system

- a) Altered density system
- b) Mucoadhesive system
- c) Size-based system

3. Delayed Release System

- a. Intestinal release system
- b. Colonic release system.

Method of preparation^[4]

Phase coacervation method

This processes consists of three steps:

- 1. Formation of three immiscible chemical phases.
- 2. Deposition of the coating.
- 3. Rigidization of the coating.

STEP 1

The process is the formation of three immiscible chemical phase a liquid manufacturing vehicle phase, a core material phase, and a coating material phase. To form the three phases, the core material is dispersed in a solution of the coating polymer, the solvent for the polymer, the solvent for the polymer being the liquid manufacturing phase. The coating material phase, an immisible polymer in a liquid phase state, is formed by utilizing one of the method by phase separation coacervation, that's is, by changing the temperature of the polymer solution or by adding a salt, nonsolvent or incompitable polymer to the polymer solution or by inducing a polymer polymer interaction. These general modes of effecting liquid-liquid phase separation.

STEP 2

It consists of depositing the liquid polymer coating upon the coating material. This is accomplished by controlled, physical mixing of the coating material (while liquid) and the core material in the manufacturing vehicle. Deposition of the liquid polymer coating around the core material occurs if the polymer is adsorbed at the interface formed between the core material and the liquid vehicle phase, and this adsorption phenomenon is a prerequisite to effective coating. The continued deposition of the coating material is promoted by a reduction in the total free interfacial energy of the system, brought about by the decrease of the coating material surface area during coalescence of the liquid polymer droplets.

STEP 3

This process involves rizidizing the coating usually by thermal, crossing-linking, or desolvation technique to form a self sustaining microcapsule.

Advantages of spansules

- 1. It reduces the dosing frequency.
- 2. It masks the taste.
- 3. Patient compliance.
- 4. It reduces the side effects.
- 5. It increases the safety margin of high potency of drugs.
- 6. It increase the stability by protecting the drug from degradation in gastro intestinal tract.
- 7. It reduces dosing frequency.
- 8. Drug will be release can be controlled by adjusting the thickness and rate of dissolution of granules thus drug will be released at different predetermined time.

Disadvantages of spansule

- 1. Dose dumping may occur.
- 2. Lack of invivo invitro correlation.
- 3. Economic limitations.
- 4. Complicated process.
- 5. The fluctuation in plasma drug level may lead to precipitation of side effects especially. drug with small therapeutic index (TI) when over medication over.
- 6. Toxicity caused due to long acting preparation is difficult to treat.

Marketed preparation

Encapsulation dissolution product of spansules	
Product Name	Active Ingredient
Benzedrine	Amphetamine sulphate
Combid	Prochlorperazine Maleate, Isopropamide Iodide
Hispril	Biphenyl Pyraline Hydrochloride
Ornade	Phenyl propanolamine hydrochloride,
	chlorpheneramine maleate
Thorazine	Chlorpheniramine hydrochloride
Balkaprofen	Ibuprofen
Dexedrine	Dextromrthorphan
Fefol	Ferrous sulphate, folic acid
Fesovit-Z	Ferrous sulphate, zinc supplements and vitamins
Thorazine	Chlorpromazine

Future approach

A new drug prepration, here the drug content are being microencapsulated and filled in a capsule shell leading to a good drug delivery. Multiple dosage forms can be deliver. Drug will be release can be controlled by adjusting the thickness and rate of dissolution of granules thus drug will be released at different predetermined time.

CONCLUSIONS

Spansules are capsules containing medicines (in form of granules), coated with materials having slow dissolving rates so that the medicament is delivered at different specific time as it increases the safety margin of high potency of drugs.

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