ISSN: 2320 - 4230

Journal of Drug Discovery and Therapeutics

Available Online at www.jddt.in

CODEN: - JDDTBP (Source: - American Chemical Society)

Volume 10, Issue 06, November-December: 2022, 41-45

Review Article

A Review article on Sustained Release Dosage Forms

Ravi Sharma[1*], Dr. Mayank Bansal[2], Dr. Vikas Agarwal[3]

[1]Research Scholar, Jaipur College of Pharmacy
[2]Professor and Principal, Jaipur College of Pharmacy
[3]Professor, Jaipur College of Pharmacy

Article Info: Received 20 September 2022; Accepted 15 November 2022

Corresponding author: Ravi Sharma

Conflict of interest: No conflict of interest.

Abstract:

For internal route of administration, oral drug delivery remains best and the most preferred for administration for various drugs. Sustained Release is also suitable for overcome the side effect of drug and also increase therapeutic efficacy of drug. The basic concepts of sustained drug delivery system optimizes of the various parameters like biopharmaceutical, pharmacokinetic and pharmacodynamics properties of a drug in such a way that therapeutic efficacy is maximized, side-effects are reduced and cure of the disease is achieved easily. In pharmaceutical field, several dosage form having several advantage so that they used, in case of the Sustained release drug delivery is betterment of patient compliance, this due to reduce dose frequency, reduction of fluctuation in steady-state drug levels, maximum utilization of the drug, increased safety margin of potent drug, reduction in healthcare cost through improved therapy and shorter treatment period. The main object of this review give the complete knowledge for the sustained release dosage and its advantage, also describe evaluation parameters of sustained release matrix tablets

Key words: Sustained release, Drug Release, Drug Properties, Matrix Tablets

Introduction

A number of terms have been used to describe the oral dosage forms that represent modified release properties; which include delayed release, repeated action, prolonged release, sustained release, extended release and controlled release. Each drug delivery system is focused at eliminating the cyclical changes in plasma drug concentration seen after administration of conventional delivery systems. Modified release dosage forms are designed to provide quick achievement of a drug plasma level that remains constant at a value within the therapeutic range of a drug for a significant period of time or achievement of a plasma concentration of a drug that delivers at a slow rate (i.e. sustained release) that stays within the therapeutic range for a longer period of time. [1]

Based on the assumption that a drug, which is to be incorporated into a modified release dosage form, confers upon the body characteristics of a one- compartment open model, then the basic kinetic design of such a product may be assumed to contain two portions, one that provides the initial loading dose, and one that provides the maintenance or sustained dose.

To ensure that the therapeutic concentration of the drug in the body remains constant, two conditions must be fulfilled, namely

1) The zero order rate of drug release must determine the absorption rate of the drug, and
2) The rate at which the drug is released from maintenance dose (and subsequently the absorption rate) should be equal to the rate of drug elimination at the required steady-state concentration a list of important terms that describe different modified release dosage forms are defined below.[2, 3]

Advantages of Sustain Release Dosage Forms

1) Decrease in frequency of intakes.
2) Reduce side effects.
3) Uniform release of drug over time.
4) Enhanced patient compliance. [4]

Disadvantages of Sustained Release Drug Delivery

1) Increased cost.
2) Toxicity due to dose dumping.
3) Unpredictable and often poor in vitro-in vivo correlation.
4) Risk of side effects or toxicity upon rapid release of contained drug (mechanical failure, chewing or masticating, alcohol intake).
5) Increased potential for first- pass clearance. [5]

Classification of Sustained Release System

The controlled release system for oral use are mostly solids and based on dissolution, diffusion or a combination of both mechanism in the control of release rate of drug.

Depending upon the manner of drug release three systems are classified as follows:

a) Continuous Release systems
b) Delayed transit and controlled release systems
c) Delayed release system

Continuous release system

Continuous release systems release the drug for a prolonged period of time along the entire length of gastrointestinal tract with normal transit of the dosage form. The various system under this category are as follow:

a. Diffusion controlled release system
b. Dissolution controlled release system
c. Dissolution and diffusion controlled release system
d. Ion exchange resin drug complexes
e. pH -independent formulation
f. Osmotic pressure controlled systems

Diffusion controlled release system

In this type of systems, the diffusion of dissolved drug through a polymeric barrier is a rate limiting step. The drug release rate is never zero order since the diffusional path length increase with time as the insoluble matrix is gradually depleted of drug. Diffusion of a drug molecule through a polymeric membrane forms the basis of this controlled drug delivery system.

The two types of diffusion-controlled release are:

1. Matrix diffusion controlled systems
2. Reservoir devices

Dissolution-controlled release systems

The drug present in such system may be the one:

a) Having high aqueous solubility and dissolution rate
b) With inherently slow dissolution rate e.g. Grisofulvin and digoxin

c) That produces slow dissolving forms, when it comes in contact with GI fluids.
Dissolution-controlled release can be obtained by slowing the dissolution rate of drug in GI medium, incorporating the drug in an insoluble polymer and coating drug particles or granules, with polymeric material of varying thickness.

Dissolution and diffusion controlled release systems

In such systems the drug core is encased in a partially soluble membrane. Pores are thus created due to dissolution of parts of membrane which permit entry of aqueous medium into the core and hence drug diffusion of dissolved drug out of the system.

Ion exchange resin-drug complexes

It is based on formulation of drug resin complex formed when ionic solution is kept in contact with ionic resins. The drug from this complex gets exchanges in gastrointestinal tract and release with excess of Na+ and Cl- present in gastrointestinal tract. This system generally utilize resin compound of insoluble cross linked polymer. They contain salt forming function group is repeating position on a polymer chain.

pH independent formulation

Most of the drug are either weak acid or weak base, the release from sustain release formulation is pH dependent. However buffer such as salt of citric acid, aminoacid, tartaric acid can be added to the formulation to help to maintain to constant pH thereby retarding pH independent drug release. A buffer sustain release formulation is prepared by mixing a basic or acidic drug one or more buffering agent, granulating with appropriate excipients and coating with gastrointestinal fluid permeable film forming polymer. When gastrointestinal fluid permeates through the membrane the buffering agent adjust the fluid inside to suitable constant pH thereby rendering a constant rate of drug release.[6]

Methods of preparation [7,8,9, 10]

Direct Compression

In this process powdered materials are compressed directly without changing the properties of the drug like physical and chemical properties.

Wet Granulation

In this method weighed quantities of drug and polymer are mixed with sufficient volume of granulating agent. After enough cohesiveness was obtained, then screening of wet mass. The granules are dried and screening of dry granules, then blending with lubricant and disintegrants to produce “running powder” tablets are compressed using a single-punch tablet compression machine.

Melt Granulation

In this process use of a substance, which is melts at relatively low temperature. This substance can be added in the molten form over the substrate, which is then heated above its melting point. Different lipophilic binders were tried by using melt granulation technique.

Hot-Melt Extrusion Process

In the hot-melt extrusion process, a mixture of the active ingredients, the thermoplastic polymers and other processing aids is fed into the barrel of the extruder through the hopper. The materials are transferred inside the heated barrel by a rotating screw.

Evaluation of Sustained release Matrix tablets: [11, 12]

Weight Variation: Twenty tablets were weighed individually and then collectively, average weight of the tablets was calculated.

Hardness: Hardness test was conducted for tablets from each batch using Monsanto hardness tester and average values were calculated.

Friability: The tablets were tested for friability testing using Roche friabilator, which revolves at 25rpm for 4min

Thickness: The thicknesses of tablets were determined using micrometer screw gauge.

Content Uniformity: Using UV Visible spectrophotometer found the amount of the drug using the calibration curve method.

Kinetic Studies

In Vitro Dissolution Study: Drug release study is generally determined in Rotating Paddles apparatus. Mainly buffer is used as a dissolution medium. The temperature of the bath maintained at 37^0C and required sample of the dissolution medium in which drug is release is taken at a regular interval and the same quantity of the medium is replace. The amounts of the drug released is determined using an UV spectrophotometer a Drug dissolved at specified time period is plot as percent release versus time.

Stability Studies: Short Term Stability Study: To determine change in vitro release profile on storage, a short term stability study of the optimal batch.

In–Vivo Methods: once the satisfactory in-vitro profile is achieved, it becomes necessary to conduct in-vivo evaluation and establish in-vitro in-vivo correlation. The various in-vivo evaluation methods are

- Clinical response
- Blood level data
- Urinary excretion studies
- Nutritional studies
- Toxicity studies
- Radioactive tracer techniques

Summary and Conclusion

The main focus of this review article has been helpful for the formulation of sustained-release matrix tablets, and factor affecting the dosage form, criteria for selection of drug for sustain release delivery with advantages and disadvantages and various polymers used to design such system. Above discussion concludes that matrix tablets are helpful to increase the efficiency of dosage in eliciting desired therapeutic response related problems associated with the conventional dosage forms with overcome the patient compliance Cost effectiveness and once-daily dose are the plus points along with other benefits. More over all these comes with reasonable cost. Hence, sustained-release matrix tablets trends towards the efficacy and optimization of the dosage form design.

References

1. Dixit N, Maurya SD, P.S.Sagar B. Sustained release drug delivery system.Indian Journal of Research in Pharmacy and Biotechnology. 2013;1: 305–10.
2. Ray Brijesh, M.M. Gupta, A Review on: Sustained Release Technology. International Journal of Therpeautics Application, 2012, Volume (8):18-23.
3. Nisargi Shah, Chintan Oza, Shital Trivedi, Nihar Shah, Shreeraj Shah, Review on Sustained Release Matrix Tablets: An Approach to Prolong the Release of Drug, JPBSR, 2015; 5(3): 315-321.
4. Lachman. L. Herbert, A.Tablet dosage Forms, The theory and practice of industrial pharmacy; 3rd edn Varghese publishing house, Bombay, 1991; 296-298,293-345,430.
5. Pawar, R.G., formulation and evaluation of pregabalin sustained release matrix tablet; Ind. J. pharm. Res & Devpt, 2011; 4(02): 153-159.
6. Parashar T, Singh V, Singh G, Tyagi S, Patel C, Gupta A, Novel oral sustained release technology:A concise review, International journal of Research and Development in Pharmacy and Life sciences, Volume 2,2013, page no.- 262- 269.

7. Ray Brijesh, M.M. Gupta, A Review on: Sustained Release Technology. International Journal of Therpeautics Application, 2012, Volume (8):18-23.

8. Nisargi Shah, Chintan Oza, Shital Trivedi, Nihar Shah, Shreeraj Shah, Review on Sustained Release Matrix Tablets: An Approach to Prolong the Release of Drug, JPBSR, 2015; 5(3): 315-321.

9. Roy D, BD Rohera Eur. J. Pharm.Sci. 2002;16 193-199. Comparative evaluation of rate of hydration and matrix erosion of HEC and HPC and study of drug release from their matrices. Eur. J. Pharm.Sci. 2002;16:193–9.

10. Harnish P, Dhrupesh P, Upendra P. Matrix Type Drug Delivery System. J. Pharm. Sci. Biosci. Res. 2011;1(3):141–57.

11. Brahmankar H, Jaiswal S. Biopharmaceutics and Pharmacokinetics A Treatise. Vallabh Prakashan; 2000:337,348–57.

12. Misal R, Atish W, Aqueel S. Matrix tablets: A promising Technique for controlled drug delivery. Indo Am. J. Pharm. Res. 2013;3(5): 3791–805.