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Review Article

Review on Formulation and Evaluation of Sustained Release Matrix Tablets

Vaishnavi Lawange, Shubhangi Ugale, Mahesh Mole

Laddad College of Pharmacy Yelgaon, Buldana 443001, Maharashtra

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ABSTRACT

Recently, sustained release pharmaceutical products became a very useful tool in medical practice, offering a wide range of actual and perceived advantages to the patients. Sustained release is also providing promising way to decrease the side effect of drug by preventing the fluctuation of the therapeutic concentration of the drug in the body. Now a days as very few drugs are coming out of research and development and already existing drugs are suffering the problem of resistance due to their irrational use specifically in case of drugs like antibiotics. Hence, change in the operation is a suitable and optimized way to make the some drug more effective by slight alteration in the drug delivery. The drug release rate is regulated by the matrix. HPMC and other release retardants can help with sustained release, so they are used as a key excipient in the formulation. The method entails compressing a mixture of medication, retardant material, and additives directly to shape a tablet with the drug embedded in a retardant matrix core; instead, granulation may be done prior to compression. Hydrophilic, hydrophobic, mineral, and biodegradable matrices may be used. To assess the drug release rate, in-vitro dissolution tests may be used. This article contains the basic information regarding sustained release formulation of matrix tablet.

INTRODUCTION

For many decades various pharmaceutical dosage forms such as tablets, capsules, suppositories, creams, ointments, liquids, aerosols, and injectable have been used for the delivery of drugs to the patients for the treatment of various diseases. The basic goal of drug therapy is to achieve a therapeutic effect. Almost 90% of all the drugs

used to produce systemic effect are administered by oral route. Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms. The oral route is the most preferred method of administration the reasons that the oral

*Corresponding Author: Vaishnavi Lawange.

Address: Laddad College of Pharmacy Yelgaon, Buldana 443001, Maharashtra

Email ✉: lawangevaishnavi20@gmail.com

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route achieved such popularity may be in part due to its ease of administration as well as the traditional belief that by oral administration the drug is well absorbed along with the gastrointestinal tract along with food stuff.

Tablets

Tablets are defined as a “solid dosage forms containing medical substances with or without suitable excipients”. The excipients may include diluents, disintegrants, binders, glidants, lubricants, flavoring agents and sweeteners to ensure the efficient tableting & elegance. The idea of forming a solid dosage form by powder compression is not new. In 1843, the first patent for a hand operated device used to form a tablet was granted. The use of tablets as a dosage form became an interest to the growing pharmaceutical industries but within pharmacies.

Advantages

Tablets are popular for several reasons

- The oral route presents a convenient and safe way of drug administration.
- Compared to liquid dosage forms, tablets have general advantage in terms of the chemical and physical stability of the dosage form.
- Tablets are convenient to handle and can be prepared in a versatile way with respect to their use and delivery of the drug.
- The preparation procedure enables accurate dosing of the drug.
- Tablets can be relatively and cheaply mass produced with robust and quality controlled production.

Disadvantages

- Some drugs were unstable in GI fluids which are unsuitable for the oral route as they would be denatured by stomach acids and first pass metabolism. Ex: Protein drugs such as insulin which are denatured by stomach acids.
- Oral route may not be suitable for drugs which have rapid onset of action and severe side effects. Ex: Salbutamol, used to treat

problems in pulmonary system can have effects on heart and circulation if taken orally.

- Drugs that cause side effects and local irritation to the gastric mucosa cannot be given orally.

Types of Tablets

Tablets are classified according to their route of administration or function. The following are the five main classification groups:

1. Tablets ingested orally

- a. Compressed tablets
- b. Multiple-compressed tablets
- c. Multi-layered tablets
- d. Sustained action tablets
- e. Enteric coated tablets
- f. Sugar coated tablets
- g. Film coated tablets
- h. Chewable tablets

2. Tablets used in the oral cavity

- a. Buccal tablets
- b. Sublingual tablets
- c. Lozenge tablets
- d. Dental cones

3. Tablets administered by other routes

- a. Implantation tablets
- b. Vaginal tablets

4. Tablets used to prepare solutions

- a. Effervescent tablets

5. Moulded tablets or tablet triturates (TT)

- a. Dispensing tablets (DT)
- b. Hypodermic tablets (HT)

Sustained release drug delivery system (SRDDs)

Any of the dosage form that maintains the therapeutic blood or tissue levels of drug by continuous release of medication for a prolonged period of time, after administration of a single dose. In case of injectable dosage forms it may vary from days to months. Sustained release describes the release of drug substance from a dosage form or delivery system over an extended period of time. Also referred to as prolonged-



release (PR), slow release (SR), sustained action (SA), prolonged action (PA) or extended-release. Sustained drug delivery may provide an immediate dose required for the normal therapeutic response, followed by the gradual release of drug in amount sufficient to maintain the therapeutic response for a specific extended period of time usually 8 – 12 hours. In the case of oral sustained released dosage form, an effect is for several hours depending upon residence time of formulation in the GIT. Conventional drug therapy requires periodic doses of therapeutic agents. These agents are formulated to produce maximum stability, activity and bioavailability. For most drugs, conventional methods of drug administration are effective, but some drugs are unstable or toxic and have narrow therapeutic ranges. Some drugs also possess solubility problems. In such cases, a method of continuous administration of therapeutic agent is desirable to maintain fixed plasma levels. To overcome these problems, controlled drug delivery systems were introduced three decades ago. These delivery systems have a number of advantages over traditional systems such as improved efficiency, reduced toxicity, and improved patient convenience. The main goal of controlled drug delivery systems is to improve the effectiveness of drug therapy. Sustained release tablets are generally taken once or twice a day during a course of treatment whereas in conventional dosage forms there is need to take 3-4 times dosage in a day to achieve the same therapeutics action. The key role behind administering a single dose of a drug is sustained release dosage forms is that it can be released over an extended period of time to maintain uniform concentration of a drug in a blood this may lead to better patient compliance and provide enhanced clinical output of the drug.

Rational for development of SRDDS

1. Formulations of SRDDS minimize dosing frequency and sustained release provides availability of a drug at action site throughout

the treatment to improve clinical efficiency of a drug molecule.

2. To reduce cost of treatment by reducing number of dosage requirement.
3. To minimize toxicity due to overdose which is often conventional dosage form.
4. To enhance the activity duration of a drug possessing short half-life.

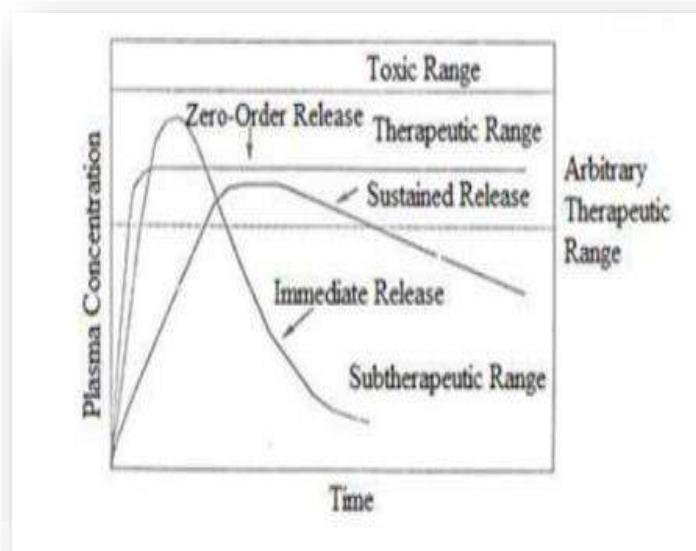


Fig : Arbitrary therapeutic range of different dosage form in blood

Advantage of sustained release drug delivery

- Reduction in blood level fluctuations of drug, thus better management of the disease.
- Reduction in dosing frequency.
- Improved efficiency of treatment.
- Maximum bioavailability with a minimum dose.
- Minimize drug accumulation with chronic dosing.
- Cure or control condition more promptly.

Disadvantage of sustained release drug delivery

- Inhibition of prompt termination of therapy
- Dosage form design
- Patient variation
- Economical factor
- Dose dumping

Advantages of Matrix System

- Easy to manufacture
- Cost effective
- Improved patient compliance
- Sustained release formulations avoid the high blood concentration
- Reduce drug toxicity by slowing down drug absorption
- Enhanced drug stability in GI milieu

Disadvantages of Matrix Tablets

- Matrix needs to be removed after drug release
- Costly in comparison to conventional dosage form
- Presence of food and gut transition time can affect the release rate

Classification of Matrix Tablets

On the basis of retardant material used matrix can be divided into five types

1. Hydrophobic matrices (plastic matrices):

In this technique hydrophobic inert polymer are used as release retarding matrix material. The drug is mixed with the hydrophobic inert polymer (e.g. polyethylene, poly vinyl chloride, ethyl cellulose) and then compressed into tablet. The drug is entrapped between the network channels of polymer particles thereby sustaining the release of drug.

2. Lipid matrices:

Lipid material is used as release retardant (e.g. carnauba waxes in combination with stearyl alcohol). Mechanism involved in drug release includes both pore diffusion and matrix erosion.

3. Hydrophilic matrices:

In this type of system a variety of hydrophilic polymers can be used, such systems are also known as swellable matrices. These polymers are more preferred than former ones as they are cost effective and a desirable drug profile can be easily obtained.

Method of Preparation of Matrix Tablet

1. Wet Granulation Technique

Milling and gravitational mixing of model drug, polymer and excipients.

- Preparation of binder solution
- Wet massing by addition of binder solution or granulating solvent
- Screening of wet mass.
- Drying of the wet granules.
- Screening of dry granules
- Blending with lubricant and disintegrants to produce “running powder”
- Compression of tablet.

2. Dry Granulation Technique

- Milling and gravitational mixing of drug, polymer and excipients
- Compression into slugs or roll compaction
- Milling and screening of slugs and compacted powder
- Mixing with lubricant and disintegrants
- Compression of tablet.

Drug Identification –

1. Organoleptic characteristics of pure drug

Organoleptic characters like color, odor and taste and powder nature of the drug were observed using visual inspection and general methods.

2. Solubility

The solubility of the drug was performed by adding excess quantity of drug to different solvents.

3. Pre-compression characteristics of pure drug

The flow property and compression characteristics of the pure drug were observed by determining the results for Bulk Density, Tapped Density, Carr’s Index, Hausner’s Ratio and Angle of Repose.

4. Melting point determination



Melting point of the drug sample was determined by open capillary tube method.

Method- The capillary tube was closed at one end by fusion and was filled with the drug on the other end by repeated tapings. The capillary tube was placed in the digital melting point apparatus. The instrument was set to automatically increase the temperature of heating bath at a rate of 10C per minute. The melting process was viewed through the magnifying lens. The temperature at which the drug started melting is recorded. This was performed thrice and their average was taken as a result.

5. Analytical Method Development

Before any product development, it is very important to develop an appropriate analytical method that provides accuracy and precision which will be used throughout the development process for the determination of assay and In-vitro dissolution process.

6. UV-Spectrum

The 10µg/ml drug solution was prepared in ethanol and a spectrum was taken in the Ultra – Violet region (200nm to 400nm) in UV visible Spectrophotometer 1800, Shimadzu (Japan). The drug peak with the highest absorbance was obtained. The observed wavelength was compared with the standard reported value.

7. FTIR Spectrum

Fourier Transform IR Spectroscopy was performed with the help of Agilent technology (Cary 630) FT-IR Spectrophotometer. The observed peaks of functional groups were compared with the peak values of the standard.

Preparation of dissolution medium

1. 0.1 N Hydrochloric acid (HCL)

- Take a clean dried 1000ml Volumetric Flask
- Add 8.5 ml Conc. HCL

- Add about 700ml water mixed & allow cool to room temperature
- Make up volume 1000ml with water
- Keep the solution for at least 1 hrs. & then carry out Standard

2. pH 6.8 Phosphate Buffer Solution: (0.2M)

- Take a clean dried 1000ml Volumetric Flask
- Add 13.87 gm. Potassium Dihydrogen Phosphate & 35.08 gm. Disodium Hydrogen Phosphate
- Add about 700ml water mixed & allow cool to room temperature
- Make up volume 1000ml with water
- Store in cold place
- pH was adjusted by using pH meter.

3. 0.2 M Sodium Hydroxide (NaOH)

- Take a clean dried 1000ml Volumetric Flask
- Add 4gm sodium hydroxide
- Make up volume 1000ml with water
- Keep the solution for at least 1 hrs. & then carry out Standard

Evaluation of Matrix tablet

1. Angle of Repose

The angle of repose is the maximum angle that the plane of powder makes with the horizontal surface on rotation. Angle of repose is helpful in assessment of flow properties of particles which could be further related to packing densities and mechanical arrangements of particles. The angle of repose of granules was determined by the fixed funnel and free standing cone method. The accurately weighed granules were taken in a funnel. The height of the funnel was adjusted in such a manner that the tip of the funnel just touched the apex of the heap of the granules. The granules were allowed to flow through the funnel freely onto the surface. The diameter of the powder cone measured and angle of repose was calculated using the following equation.

$$\tan \theta = h/r$$



$$\theta = \tan^{-1} h/r$$

Where,

h = height of the powder heap

r = radius of the powder heap

θ = is the angle of repose.

Table: Standard value of angle of repose

Sr. No.	Angle of repose	Flow property
1	25-30	Excellent
2	30-35	Good
3	35-40	Fair
4	40-45	Poor

2. Determination of Bulk Density and Tapped Density

Bulk density of a compound varies substantially with the method of crystallization, milling or formulation. It is of great importance when one considers the size of a high – dose capsule product or the homogeneity of a low dose formulation in which there are large differences in drug and excipient densities. In addition to bulk density, it is frequently desirable to know the true density of a powder for computation of void volume or porosity of packed powder beds. An accurately weighed quantity of the granules/ powder (W) was carefully poured into the graduated cylinder and volume (V₀) was measured. Then the graduated cylinder was closed with lid and set into the tap density tester. The density apparatus was set for 100 tabs and after that the volume (V_f) was measured and continued operation till the two consecutive readings were equal. The bulk density and the tapped density were calculated using the following formula.

$$\text{Bulk density} = W/V_0$$

$$\text{Tapped density} = W/V_f$$

Where,

W = Weight of the powder

Table: Standard value of Hausner's ratio and compressibility Index.

V₀ = Initial volume

V_f = final volume

3. Carr's Compressibility Index

An indirect method of measuring powder flow from bulk densities was developed by Carr. The percentage compressibility of a powder was a direct measure of the potential powder arch or bridge strength and stability. Carr's index of each formulation was calculated according to equation given below:

$$\text{Carr's index} = \left[\frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \right] \times 100$$

Where,

TD = Tapped Density

BD = Bulk Density

Table: Standard value of Carr's Index

Sr. No.	% Compressibility	Flow ability
1	5 - 15	Excellent
2	12 - 16	Good
3	18 - 21	Fair to Passable
4	23 - 35	Poor
5	33 - 38	Very Poor
6	> 40	Extremely Poor

4. Hausner's Ratio indicates the flow

properties of the powder and is measured by the ratio of tapped density to bulk density. It is the ratio of tapped density and bulk density. Hausner's found that this ratio was related to interparticle friction and, as such, could be used to predict powder flow properties. Generally a value less than 1.25 indicates good flow properties, which is equivalent to 20% of Carr's index.

$$\text{Hausner's} = \frac{\text{Tapped density}}{\text{Bulk density}}$$



Sr. No	Hausner's Ratio	Flow character	Compressibility index
1	1.0-1.111	Excellent	≤ 10
2	1.12 – 1.18	Good	11-15
3	1.19 – 1.25	Fair	16-20
4	1.26 – 1.34	Passable	21-25
5	1.35 – 1.45	Poor	26-31
6	1.46 – 1.59	Very poor	32-37
7	>1.60	Very very poor	≥ 38

Post compression parameters

All the prepared matrix tablets were evaluated for following official and unofficial parameters.

1. Appearance

Tablet from each formulation were randomly selected and organoleptic properties such as color, taste, and shape were evaluated.

2. Thickness

Thickness was measured using a calibrated screw gauge meter. Five tablets of the formulation were picked randomly and thickness was measured individually.

3. Hardness

Hardness (diametric crushing strength) is a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength. The tablet should be stable to mechanical stress during coating, packaging transportation and also during patient handling. The degree of hardness varies with the different manufactures and with the different types of tablets. The permissible limit for sustained release tablets is 4-12 kg/cm². The hardness of tablets for fast dissolving tablets is usually kept low for easy disintegration in the mouth. The hardness was tested using Pfizer or Monsanto hardness tester.

4. Friability

Twenty tablets were weighed and placed in the Roche Friabilator and apparatus was rotated at 25 rpm for 4 minutes. After revolutions, the tablets were dedusted and

weighed again. The percentage friability was measured using formula,

$$\text{Percentage friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Where,

% F = Friability in percentage

W = Initial weight of tablets

Wt = Weight of tablets after revolution

Acceptance criteria for % friability % weight loss should be less than 1%.

5. Weight variation:

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation if not more than two of the individual tablet weight deviate from the average weight.

Table: Percentage weight deviations.

Sr. No.	Average Weight	% difference
1	130 mg or less	10
2	130 – 324 mg	7.5
3	324 mg and greater	5

6. In vitro dissolution studies

The release rate of sustain tablets was determined. The dissolution test was performed using United States Pharmacopoeia (USP) type II (paddle) apparatus, 900 ml of phosphate buffer of pH 6.8 at $37 \pm 0.5^\circ\text{C}$ and 50 rpm. A sample (10) of the solution was withdrawn from the dissolution apparatus at the appropriate time



for 12 hours, and the samples were replaced with fresh dissolution medium. The samples were diluted into a suitable concentration with phosphate buffer. Absorbance of these solutions was measured by using a UV/Visible double-beam spectrophotometer.

Table: Details of dissolution test

Dissolution test apparatus	USP II (Paddle)
Speed	50 rpm
Time interval	0.5, 1, 2, 4, 6, 8, 10, 12h
Medium used	Phosphate buffer pH 6.8
Temperature	37 ± 0.5 °C.

7. Moisture content

Initially 5 gm of weighed granules were taken and kept for drying at 105°C for a required time in an oven. Then removed and again reweighed and note as final weight. The difference in weight was note as moisture content.

Moisture content = Initial weight - Final weight / Initial weight × 100

CONCLUSION

The present work was to formulate and evaluate sustain release Matrix tablets of model drug by using combination of natural and synthetic polymer as release retardant to sustain the drug release from Matrix tablet. The sustained release drug delivery was a promising approach to achieve a prolonged therapeutic action of drug. The cumulative percentage drug was decreased by increase in polymer concentration. FTIR studies proved that there was no chemical interaction in drug and polymer of the developed matrix tablets

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