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Review On Sustained Release Tablets

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Abstract: Sustained release (sr) tablets are innovative oral dosage forms designed to deliver a drug at a predetermined rate for a prolonged period, maintaining constant therapeutic drug level in blood stream. The main objective of developing sustained release formulation is to enhanced patient compliance by reducing dosing frequency minimizing side effects and improving the efficacy of drug therapy. These tablets are formulated using various polymer such as hydroxypropyl methylcellulose (HMPC) ethyl cellulose and carbopol which control the drug release rate through diffusion or erosion mechanisms. The design approaches include matrix system, reservoir system and osmotic- controlled release systems. The release behavior of the drug depends on physiochemical properties like solubility, particle size and type of polymer used. Sustained release tablets are particularly useful for chronic conditions and pain management where long term therapy is essential. This drug delivery system not only maintain steady plasma drug concentration but also reduces fluctuation associated with conventional dosage forms. Therefore, sustained release technology represents a significant advancement in modern pharmaceutical formulation and drug delivery science.

Key Words: Sustained release tablet, Controlled drug delivery, matrix system, polymers Prolonged action, oral dosage form, patient compliance.

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. Sustained release tablets have been developed to release the drug slowly at a predetermined rate maintaining constant therapeutic levels over an extended period. Sustained release formulation are designed to provide a prolonged therapeutic effect by maintaining a steady drug concentration with in the therapeutic window, thus minimizing the peaks and throughs associated with conventional dosage forms. They are especially useful for drugs with short half life and those requiring long term therapy. In sustained release tablets, the sustained release tablets, the drug release is controlled through various mechanism such as diffusion, dissolution or a combination of both depending on the polymer and formulation design. the development of sustained release systems also helps reduce the frequency of dosing improve patient convenience and enhance the bioavailability of certain drugs.

Various natural and synthetic polymers such as hydroxypropyl methylcellulose (HPMC), ethyl cellulose, guar gum and xanthan gum are commonly used in the formulation of sustained release tablets. The proper selection of these polymers and excipients is crucial to achieving the desired release profile and ensuring the stability of dosage form. Hence, sustained release technology has become an important area of research in the Indian pharmaceutical industry, as it not only enhances therapeutic efficacy and patient compliance but also provides an economic advantage by reducing the overall dosage requirement.

1. Modified release dosage form

Modified release dosage forms defined by United States Pharmacopoeia as those dosage forms whose drug release characteristics of time course or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms.

2. Controlled release

The drug is release at constant (zero order) rate and the drug concentration obtained after administration is in variant with time.

3. Delayed release

The drug is released at a time other than immediately after administration.

4. Extended release

Extended release refers to the slower release of the drug so that plasma concentration are maintained at therapeutic level for extended period of time usually between 8&12 hr.

5. Prolonged release

The drug is provided for absorption over a longer period of time than from conventional dosage form. However, there is an implication that onset is delayed because of an overall slower release rate from the dosage form.

6. Repeat action

Repeat action indicates that an individual dose is released fairly soon after administration and second or third doses are subsequently released at intermittent intervals.

7. Sustained release

The drug is released slowly at a rate governed by the delivery system .

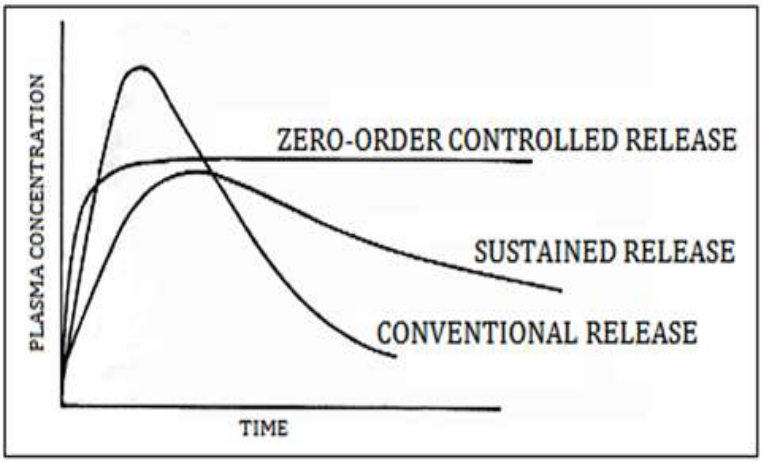

Fig 1: Plasma drug concentration profile for conventional release Sustained release and zero order controlled

Gastrointestinal Tract (GIT)

The human gastrointestinal tract, or GI tract, or GIT is an organ system responsible for consuming and digesting foodstuffs, absorbing nutrients, and expelling waste. The tract consists of the stomach and intestines and is split into the upper and lower gastrointestinal tracts. The GI tract includes all structures across the mouth and the anus. On the other hand, the digestive system is a broader term that comprises other structures, including the digestive organs. The GI tract releases hormones to help regulate the digestive process. These hormones, including gastrin, secretin, cholecystokinin, and ghrelin. The track is divided into upper and lower tracts, and the intestines small and large parts

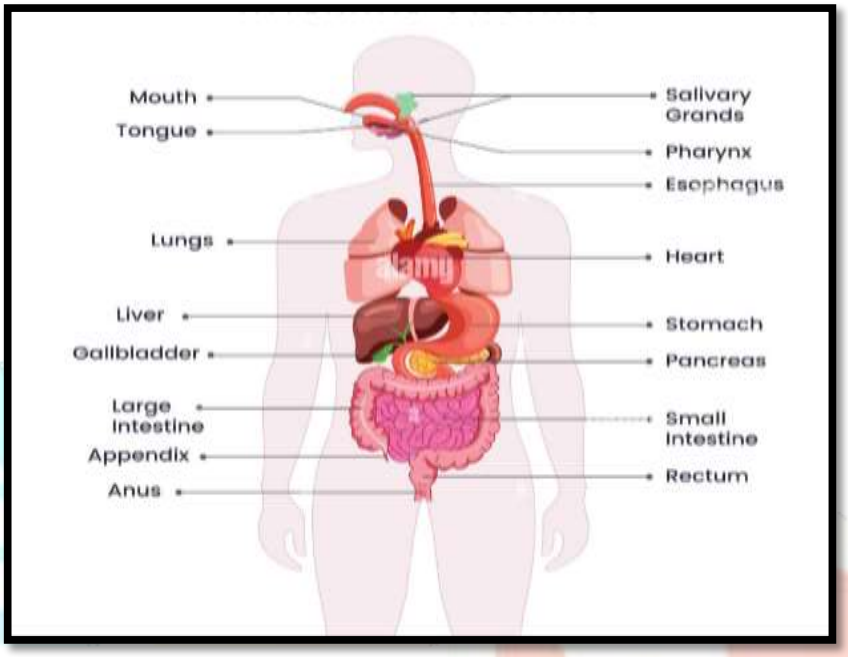

Fig 2: Upper gastrointestinal tract (stomach)

Upper Gastrointestinal Tract

The upper gastrointestinal tract composed of the esophagus, stomach, and duodenum. The exact demarcation across the upper and lower tracts is the suspensory ligament of the duodenum (also known as the Ligament of Treitz). This delineates the embryonic borders across the foregut and midgut and is also the division commonly used by clinicians to describe gastrointestinal bleeding as being of “upper” or “lower” origin.

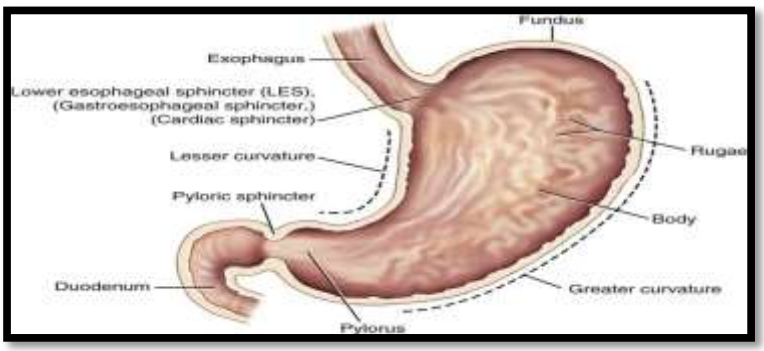

Fig 2.1: Upper gastrointestinal tract (stomach)

Lower Gastrointestinal Tract

The lower gastrointestinal tract comprises most of the small intestine and all of the large intestine. In human anatomy, the intestine (or bowel, hose, or gut) is the segment of the gastrointestinal tract extending from the pyloric sphincter of the stomach to the anus and, in humans and other mammals, consists of two segments, the small intestine, and then large intestine. In humans, the small intestine is more likely subdivided into the duodenum, jejunum, and ileum while the large intestine is subdivided into the cecum, colon, rectum, and anal canal.

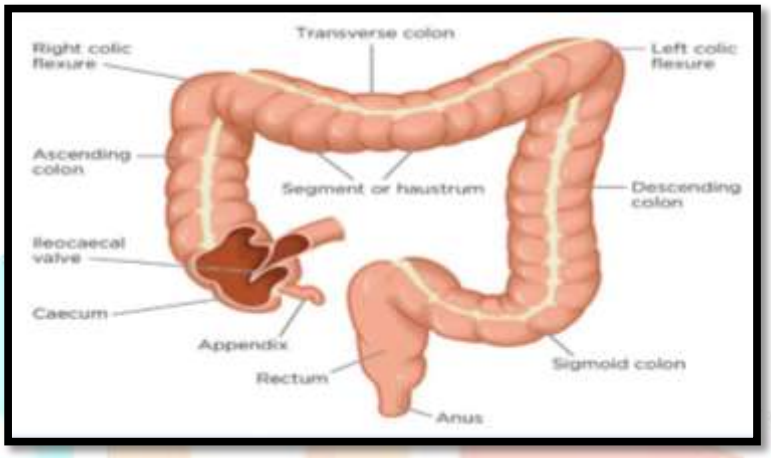

Fig 2.2 : Lower gastrointestinal tract (Intestine

RATIONALE OF DEVELOPING SR TABLETS

- To extend the duration of the action of the drug
- To reduce the frequency of dosing
- To minimize the fluctuation in plasma level
- Improved drug utilization
- Less adverse effects

ADVANTAGES OF SUSTAINED RELEASE TABLETS

1. The aggregate sum of medication regulated can be decreased
2. Improved Productivity in treatment
3. Economy
4. Uniform release of drug over time
5. Better patient Compliance

DISADVANTAGES OF SUSTAINED RELEASE TABLETS

1. Cost production is high compared to conventional dosage form.
2. In vivo and vitro correlation
3. Toxicity due to dose dumping
4. Need for additional patient education and counseling.
5. First pass metabolism has increased potential.

METHODS FOR PREPARATION OF SUSTAINED RELEASE TABLETS

1. Direct Compression:

This is the simplest and most commonly used method. It involves the following steps

- Weighing and blending: Active pharmaceutical ingredients (API) and excipients like polymer, diluent and lubricant are weighed and mixed to ensure uniform distribution.
- Compression: The mixture is compressed directly without changing the properties of the drug like physical and chemical properties.

2. Wet Granulation

The wet granulation method is the most common technique used to prepare granules for tablet and capsule production. It involves the following steps

- Preparation of wet mass: The drug, polymer and other excipient are mixed and binding solution is added to form a wet mass.
- Granulation: The wet mass is passed through a sieve to form granules.
- Drying: The granules are dried to remove moisture.
- Compression: Dried granules are compressed into tablets.

3. Dry Granulation

The dry granulation method is process used in pharmaceutical manufacturing to form granules without using any liquid solution. It involves the following steps.

- Weighing and mixing: The active pharmaceutical ingredient (API) and excipients like filler or binder are accurately weighed and mixed uniformly.
- Compression or compaction: The mixed powder is then compressed into large tablets called slugs using a tablet press or compacted into ribbons using roller compactor.

- Milling: The slugs or ribbons are broken down and milled into granules of the desired size.
- Sieving: The milled granules are passed through sieves to obtain uniform particle size.
- Blending: The granules are mixed with lubricants or glidants to improve flow properties.
- Compression or Filling: The final granules are compressed into tablets or filled into capsules.

4. Melt Granulation:

Meltable compounds act as liquid binding agents during the melt granulation process.

It involves the following steps.

- Mixing: Drug and excipients are mixed with meltable binder like polyethylene glycol, waxes etc.
- Heating: The mixture is heated until the binder melts, forming granules.
- Cooling and Compression: The granules are cooled, sieved and compressed into tablets.

EVALUATION OF SUSTAINED RELEASE TABLETS

1) Pre-Compression Parameter

I. Bulk density (Bd): It is the ratio of powder to bulk volume. The bulk density depends on particle size distribution, shaped and cohesiveness of particles. Accurately weighed quantity of powder was carefully poured into graduated measuring cylinder through large funnel and volume was measured which called initial bulk volume. Bulk density is expressed in gm/cc and is given by.

$$Db = M / Vo$$

Where, Db = Bulk density (gm / cc)

M = Mass of power (g)

Vo = Bulk volume of powder (cc)

II. Tapped density (Dt): Ten grams of powder was introduced into a clean, dry 100ml measuring cylinder. The cylinder was then tapped 100 times from a constant height and tapped volume was read. It is expressed in gm / cc and is given by,

$$Dt = M / Vt$$

Where, Dt = Tapped density (gm /cc)

M = Mass of powder (g)

Vt = Tapped volume of powder (cc)

III. Compressibility Index: One of the important that can be obtained from bulk and tapped density determinations is the percent compressibility or the carr's index which is determined by following equation,

$$\text{Compressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

Sr.no	Carr's Index	Flow Properties
1	5 -15	Excellent
2	12 -15	Good
3	18 - 21	Fair to Passable
4	23 - 30	Poor
5	33 - 38	Very Poor
6	>40	Very Very Poor

Table 1: Grading of powder for their flow properties according to Carr's index

IV. Hausner Ratio:

Hausner ratio = Tapped density / Bulk density

Values of Hausner ratio; < 1.25

Good Flow > 1.25: Poor flow

If Hausner ratio is between 1.25-1.5 flow can be improved by addition of glidants.

V. Angle of repose (ɵ): It is defined as the maximum angle possible between the surface of pile of the powder and horizontal plane. Fixed funnel method was used. A funnel was fixed with its tip at a given hight (h), above a Flat horizontal surface on which a graph paper was placed. powder was carefully poured through a funnel till the apex of conical pile just touches the tip of funnel. The angle of repose was then calculated using the formula,

$\tan \theta = h / r$

$\theta = \tan - 1 (h / r)$

where, ɵ = angle of repose

h = height of pile

r = radius of the base of the pile

Sr.no	Angle of repose	Flow Properties
1	<25	Excellent
2	25− 30	Good
3	30 – 40	Passable
4	>40	Very poor

Table 2: Comparison between angles of repose and flow property

VI. Total Porosity: Total porosity was determined by measuring the volume occupied by a selected weight of a powder (Vbulk) and true volume of the powder blend (The space occupied by powder exclusive of space greater than the intermolecular spaces V).

Porosity (%) = Vbulk / Vbulk × 100

VII. Flow Rate: Flow rate of granules influenced the filling of die cavity and directly affects the weight of the tablet produced.

2) Post Compression Parameters

I. Thickness and Diameter: Control of physical dimension of the tablet such as thickness and diameter is essential for consumer acceptance and tablet uniformity. The thickness and diameter of the tablet was measured using verniercalipers. It is measured in mm.

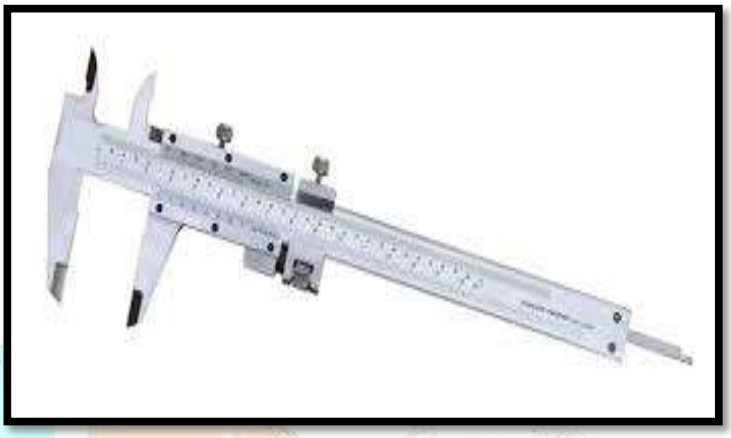

Fig 3 : Verniercalipers

II. Hardness test: The resistance of tablet to shipping or breakage under the condition of storage, transportation and handling before usage depends on its hardness. The hardness of tablet measured by Mansanto hardness tester and also can be measured by other tester like Pfizer tester. The tablet was held between a fixed and moving jaw. Scale was adjusted to zero load was gradually increased until the tablet fracture. The value of the load at that point gives a measure of hardness of the tablet. Hardness was expressed in kg/cm^2.

Fig 4 : Mansanto Hardness tester

Fig 4.1: Pfizer hardness tester

III. Friability: A tablet property related to hardness is friability, and the measurement is made by use of the Roche friabilator. Twenty tablets are weighed and placed in friabilator. The chamber is roated for 4 minutes at a speed of 25rpm. The tablets are removed from the chamber and weighed again. Loss in wight indicates friability. The tablets to be consider of good quality if loss in weight is less than 0.8 %. It calculated by

$$\% \text{ Friability} = W_o - W/W_o \times 100$$

Where, W_o = Initial weight of Twenty tablet

W = Weight of Twenty tablet after 100 revolution

Fig 5: Friability tester

IV. Weight Variation: The weight of the tablet being made in routinely measured to ensure that contains the proper amount of drug. The USP weight variation test was done by weighing 20 tablets individually, calculating the average. The tablet meets the USP test if not more than 2 tablets are outside the percentage limits and if no tablets differ by more than 2 times the percentage limit**.**

$$PD = \frac{(Wavg)-(Winitial)}{(Wavg)} \times 100$$

Where, PD = Percentage deviation

Wavg = Average weight of tablet

W initial = individual weight of tablet

V. **Uniform of drug content:** Five tablets of various formulations weighed individually and powdered. The powder equivalent to average weight of tablets was weighed and drug was extracted in phosphate buffer pH 6.8 the drug content was determined measuring the absorbance at 262.4 nm after suitable dilution using a UV/ Visible spectrophotometer (UV – 1800).

CONCLUSION

Sustained release tablets are an effective dosage form designed to release the drug slowly over an extended period, improving patient compliance and maintaining a steady therapeutic effect. They help reducing dosing frequency, minimize fluctuations in plasma drug levels and decreases side effects associated with peak concentrations. By using suitable polymers and formulation techniques sustained release ensure controlled drug delivery and improve oveall therapeutic outcomes. Thus, they play a significant role in modern pharmaceutical technology and patient centred therapy.

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