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A Review on Sustained Release Tablet

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Abstract: *Recently, extended-release pharmaceutical products have emerged as invaluable tools in medical practice, presenting a myriad of tangible and perceived benefits to patients. Sustained release offers a promising avenue to mitigate the side effects of drugs by preventing fluctuations in therapeutic drug concentrations within the body. In the contemporary landscape, the scarcity of new drugs from research and development, coupled with the rising issue of resistance, especially with antibiotics, necessitates a shift in operational strategies. This shift involves optimizing existing drugs to enhance efficacy through slight modifications in drug delivery methods.*

Sustained release not only serves as a means to address drug resistance but also holds the potential to minimize the adverse effects of medications by regulating the therapeutic concentration of the drug in the body. The release mechanisms in such systems encompass both dissolution-controlled and diffusion-controlled processes. Improper formulation of drugs may result in rapid drug release, leading to the onset of toxic concentrations upon oral administration.

This article provides fundamental insights into sustained-release formulations, encompassing various types of such formulations.

Keywords: integral to this discussion include matrix tablets, sustained-release polymers, patient convenience, compliance, and the specific drugs Diclofenac, Alprazolam, Aceclofenac, and Progesterone

I. INTRODUCTION

All pharmaceutical products designed for systemic delivery through the oral route, regardless of the delivery mode (immediate, sustained, or controlled release) and the dosage form design (solid dispersion or liquid), must be developed in alignment with the inherent characteristics of gastrointestinal physiology, pharmacokinetics, pharmacodynamics, and formulation design. This alignment is crucial to adopt a systemic approach for the successful development of an oral pharmaceutical dosage form. [1]

Various terms such as sustained release, prolonged release, modified release, extended-release, or depot formulations are employed to characterize drug delivery systems engineered to achieve or prolong therapeutic effects by continuously dispensing medication over an extended timeframe following the administration of a single dose. [2]

The term "sustained release" has been a long-standing presence in medical and pharmaceutical literature, persisting for several decades. It consistently refers to a pharmaceutical dosage form designed to impede the release of a therapeutic agent, causing a delay and/or prolongation in its appearance in the systemic circulation. This intentional modulation results in a sustained plasma profile, with the onset of pharmacological and the therapeutic effect's duration prolonged. [3]

The oral route stands out as the most widely utilized method for drug administration, attributed in part to its ease of use and the inherent flexibility in dosage form design afforded by gastrointestinal physiology, surpassing that of most other administration routes. [4]

A clinical investigation involving 600 participants aged between 50 and 69 disclosed that 35% of the overall population experienced some level of dysphagia. [5]

Over the past two decades, there has been a notable surge in interest surrounding sustained-release drug delivery systems. This heightened focus can be attributed to several factors, including the prohibitive costs associated with developing new drug entities, the expiration of existing international patents, the discovery of new polymeric materials

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conducive to prolonged drug release, and the advancements in therapeutic efficacy and safety understanding through these delivery systems. [6]

1.1 PRINCIPLE OF SUSTAINED RELEASE DRUG DELIVERY SYSTEMS

Sustained release drug delivery systems operate on the principle that active ingredients are gradually released into an absorption pool by conventional dosage forms. The solution of the drug at the absorption site is referred to as the absorption pool. Ke, Kr, and Ka represent the first-order rate constants for drug elimination, drug release, and drug absorption, respectively.

For immediate-release dosage forms, Kr >>>Ka indicates that the absorption of the drug across a biological membrane is the rate-limiting step in delivering the drug to its target area. On the other hand, for non-immediate release dosage forms, Kr <<<<Ka, signifying that the rate-limiting step is the release of the drug from the dosage form. This scenario follows zero-order kinetics, as expressed by the equation:

$$Kr^{\circ} = \text{Rate In} = \text{Rate Out} = Ke\ CdVd$$

Where,

Kr°: Zero-order rate constant for drug release (Amount/time),

Ke: First-order rate constant for overall drug elimination time,

Cd: Desired drug level in the body Amount/volume, and

Vd:Volumespaceind4whichthedrugisdistributedinlitre.

In an ideal controlled-release system employing zero-order kinetics, multiple dosing regimens mirror those used for a constant intravenous infusion. The release of the drug in a consistent, linear fashion simplifies the administration schedule. However, for controlled-release systems with kinetics other than zero-order, the design of multiple dosing regimens becomes more intricate and requires careful consideration of the specific release profile and characteristics of the system. [7]

1.2 TERMINOLOGY

Modified release delivery systems are conveniently categorized into four main groups:

A. Delayed Release:

Systems employ repetitive, intermittent dosing of a drug from one or more immediate-release units within a single dosage form. Examples include repeat action tablets, capsules, and enteric-coated tablets where timed release is achieved by a barrier.

B. Sustained Release:

Over the last two decades, there has been a remarkable increase in interest in sustained-release drug delivery systems. This surge is attributed to factors such as the prohibitive cost of developing new drug entities, the expiration of existing international patents, the discovery of new polymeric materials suitable for prolonging drug release, and improvements in therapeutic efficiency and safety achieved by these delivery systems. In contemporary applications, sustained-release technology is also being applied to veterinary products. These systems facilitate a slow release of the drug over an extended period, offering control—whether temporal or spatial—over drug release in the body. In other words, the system effectively maintains constant drug levels in the target tissue or cells.

B.1 Controlled Release:

A subtype of sustained release, controlled release systems provide a regulated and predictable release of the drug, contributing to improved therapeutic outcomes.

B.2 Extended-Release:

Another subtype of sustained release, extended release systems similarly aim to provide a prolonged and consistent release of the drug over an extended timeframe.

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C. Site-Specific Targeting:
Delivery systems are designed to release drugs at specific anatomical locations within the body.

D. Receptor Targeting:
Systems engineered to target specific receptors, allowing for a more precise and targeted drug delivery.

1) Controlled Release:
Encompasses any drug delivery system designed to achieve a slow release of the drug over an extended period, providing sustained therapeutic effects.

2) Extended-Release:
Pharmaceutical dosage forms that release the drug at a slower rate than the normal manner, maintaining a predetermined rate and thereby reducing the dosage frequency by half.

C) Site-Specific Targeting:
Involves delivering a drug directly to a specific biological location, typically adjacent to or within the diseased organ or tissue.

D) Receptor Targeting:
Similar to site-specific targeting, receptor targeting systems direct drugs specifically to particular receptors within an organ or tissue. Both site-specific targeting and receptor targeting systems address the spatial aspect of drug delivery and are considered sustained drug delivery systems. [8]

The immediate-release (IR) drug delivery system lacks features such as dose maintenance, sustained release rate, and site targeting. In contrast, oral sustained drug delivery offers potential advantages like maintaining a sustained release rate and dose maintenance in plasma. Sustained-release (SR) formulations often incorporate swelling polymers or waxes, or a combination of both, to control the release rate. The use of reservoir systems is also a well-established method for controlling the release rate.

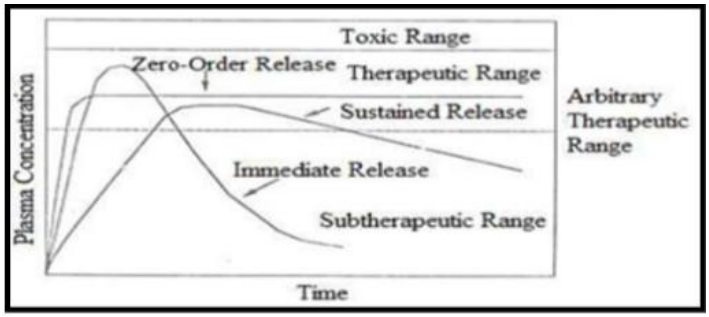

FIG1.1 Ideal Plasma Concentration Curves For Immediate Release, Zero Order Release, Sustained Release Drug Delivery System

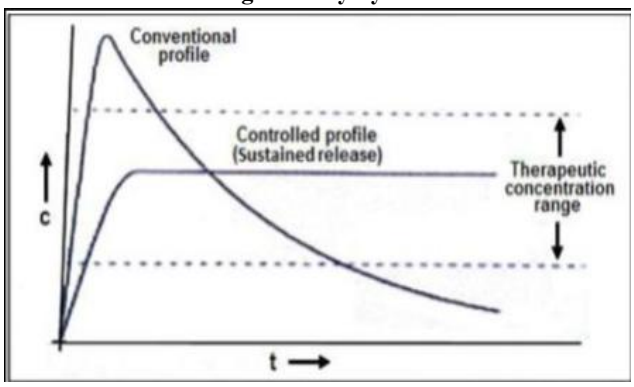

FIG1.2 Comparison of conventional and controlled release profiles

1.3] TYPES OF SUSTAINED RELEASE SYSTEM:

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1) Dissolution-Controlled Release System:[9]

In these products, the rate of drug release is governed by slowly soluble polymers or microencapsulation. The drug becomes available for dissolution once the coating is dissolved. By adjusting the thickness and composition of the coat, the rate of drug release can be controlled. Some formulations include a fraction of the total dose as an immediate-release component to provide a pulse dose soon after administration. Pellet dosage forms of diffusion- or dissolution-controlled products can be encapsulated or get ready as a tablet. Dissolution-controlled products can be further subdivided into two types:

a) Encapsulation Dissolution Control: - The dissolution is controlled through the encapsulation of the drug.

b) Matrix Dissolution Control: - The dissolution is controlled through the matrix in which the drug is dispersed.

2) Diffusion-Controlled Release System:

In these systems, the release rate of the drug is primarily determined by the drug's diffusion through a matrix or membrane.

3) Bio-Erodible and Combination Diffusion and Dissolution System:

These systems involve erosion or dissolution of a bio-erodible matrix, and in some cases, a combination of both diffusion and dissolution mechanisms.

4) Osmotically Controlled Release System:

In this type, drug release is regulated by osmotic pressure, typically achieved using an osmotically active core.

5) Ion Exchange Systems:

Drug release in these systems is controlled through ion exchange processes.

Each type of sustained release system offers unique advantages and is tailored to suit specific drug delivery requirements.

a) Encapsulation Dissolution Control:

This method involves coating individual particles or granules of the drug with a slow-dissolving material. The coated particles can be directly compressed into tablets or placed in capsules. Microencapsulation controls the rate of dissolution of the drug, regulating its availability for absorption. Once the coating is dissolved, the drug becomes accessible for dissolution. The rate of drug release can be managed by varying the thickness and composition of the coating. It is important not to chew these products as damage to the coating may occur. Encapsulated pelleted products offer an advantage in that the onset of absorption is less sensitive to stomach emptying. The entry of pellets into the small intestine, where the majority of drug absorption occurs, is typically more uniform than with non-disintegrating sustained-release tablet formulations.

b) Matrix Dissolution Control:

In this system, an alternative approach involves compressing the drug with a slow-dissolving carrier. The rate of drug release is controlled by factors such as the rate of penetration of the dissolution fluid into the matrix, porosity, the presence of hydrophobic additives, and the wet ability of the system and particle surface.

Diffusion – Controlled Release System

In these systems, water-insoluble polymers control the flow of water and subsequent release of the dissolved drug from the dosage form. Diffusion occurs as the drug passes through the polymer forming the controlled release device, either through pores in the polymer matrix or between polymer chains. There are two broad categories of diffusion-controlled release systems:

A. Reservoir Devices:

In this system, a water-insoluble polymeric material encases the core of the drug. The drug will partition into the membrane and exchange with the fluid surrounding the particles or tablet. The active agent is released to the surrounding environment through a diffusion process across the rate-limiting membrane. In reservoir systems, the drug delivery rate remains fairly constant.

B. Matrix Devices:

In matrix devices, the drug or active ingredient is dispersed in a polymer matrix to create a homogeneous system known as a matrix system. Diffusion occurs as the drug passes from the polymer matrix into the external environment. As the

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release progresses, the rate typically decreases with this type of system, as the active agent has an increasingly longer distance to travel, necessitating a longer diffusion time for release.

3. Ion Exchange System:

Extended-release drug-resin complexes, also known as "resonates," have been successfully used commercially. The drug is bound to the resin and released through an exchange with appropriately charged ions in contact with the ion exchange groups. This technique applies to certain drugs that possess specific characteristics in terms of their relative affinity for the polymers being used.

TYPES OF ION EXCHANGE RESINS:

Cationic Exchange Resin:

Contains acidic functional groups.

Anion Exchange Resin:

Contains basic functional groups.

These ion exchange resin systems exhibit enhanced drug retention capabilities, reducing the risk of dose dumping and consequently lowering the probability of toxicity. Additionally, the polymeric and ionic properties of ion exchange resins contribute to a more uniform drug release compared to simple matrices. [10]

1.4 FACTORS AFFECTING THE ORAL SUSTAIN RELEASE DOSAGE FORM DESIGN

A) Pharmacokinetics and Pharmacodynamics Factors:

Biological Half-life:

Drugs with a biological half-life of 2-8 hours are considered suitable candidates for sustained-release dosage forms, as this can reduce dosing frequency. However, a limitation exists for drugs with very short biological half-lives, as they may require excessively large amounts of the drug in each dosage unit to maintain sustained effects, making the dosage form impractically large.

Absorption:

The rate of absorption in sustained formulations depends on the release rate constant of the drug from the dosage form. For drugs absorbed by active transport, absorption is limited to the intestine.

Distribution:

The distribution of drugs into tissues is a crucial factor in overall drug elimination kinetics. It not only lowers the concentration of circulating drug but can also be rate-limiting in its equilibrium with blood and extravascular tissue. Consequently, the apparent volume of distribution assumes different values be conditional on the time course of drug disposition. Therefore, for the design of sustained-release products, information on the drug's disposition is essential.

Metabolism:

The metabolic conversion of a drug should be considered before transforming it into another form. Successful sustained-release products can be developed when the location, rate, and extent of metabolism are known. [11]

B) Drug Properties Relevant to Sustain Release Formulation:

Dose Size:

A dose size of 500-1000mg is considered maximal for a conventional dosage form, and this holds for sustained-release dosage forms as well. Considering dose size serves as a parameter for safety in administering large amounts with a narrow therapeutic range.

Ionization, pKa, and Aqueous Solubility:

Most drugs are weak acids or bases. For a drug to be absorbed, it must dissolve in the aqueous phase surrounding the site of management and then partition into the absorbing membrane.

Partition Coefficient:

The bioavailability of a drug is significantly influenced by the partition coefficient, as biological membranes are lipophilic. The transport of a drug across the membrane depends on its partition coefficient. Drugs with low partition

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coefficients are considered poor candidates for sustained-release formulations as they tend to be localized in the aqueous phase (e.g., Barbituric acid), and vice versa.

Drug Stability:

Orally administered drugs encounter acid-base hydrolysis and enzymatic degradation. In cases where the drug is unstable in the stomach, a drug release system that provides medication over an extended period is preferred. Conversely, if the drug is unstable in the intestine, it may face issues of lower bioavailability. [12]

1.5 METHOD OF PREPARATION OF MATRIX TABLET:

1) Wet Granulation Technique:

Milling and gravitational mixing of the drug, polymer, and excipients.
Preparation of binder solution.
Wet massing by the addition of the binder solution or granulating solvent.
Screening of the wet mass.
Drying of the wet granules.
Screening of dry granules.
Blending with lubricant and disintegrants to produce a "running powder."
Compression of the tablet. [13]

This wet granulation technique is a common method for preparing matrix tablets, allowing for effective blending, granulation, and compression to produce tablets with sustained-release characteristics.

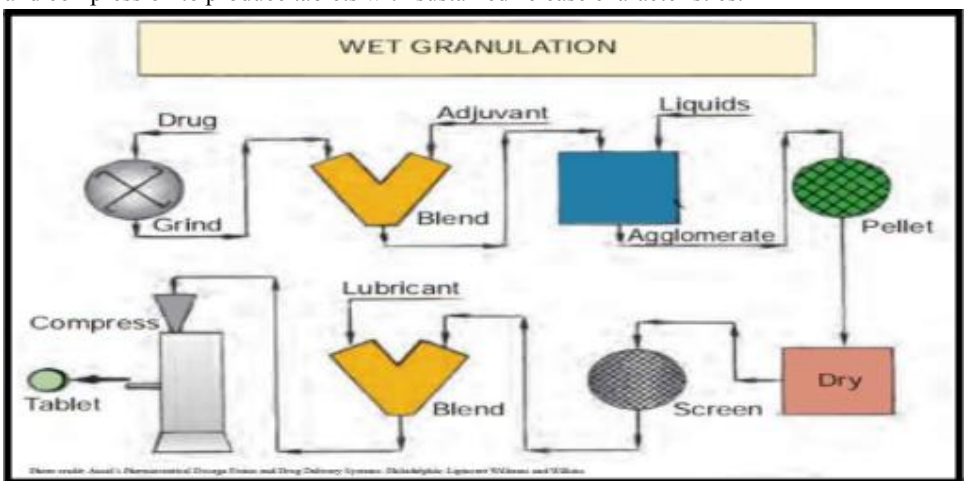

FIG.1.3 Wet Granulation Technique

2) Dry Granulation Technique:

Milling and gravitational mixing of the 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 the tablet. [13]

Dry granulation is an alternative technique for preparing matrix tablets. It involves the compression of the drug and excipients into compacted masses or slugs, followed by milling and screening to obtain granules. These granules are then mixed with lubricants and disintegrants before final tablet compression.

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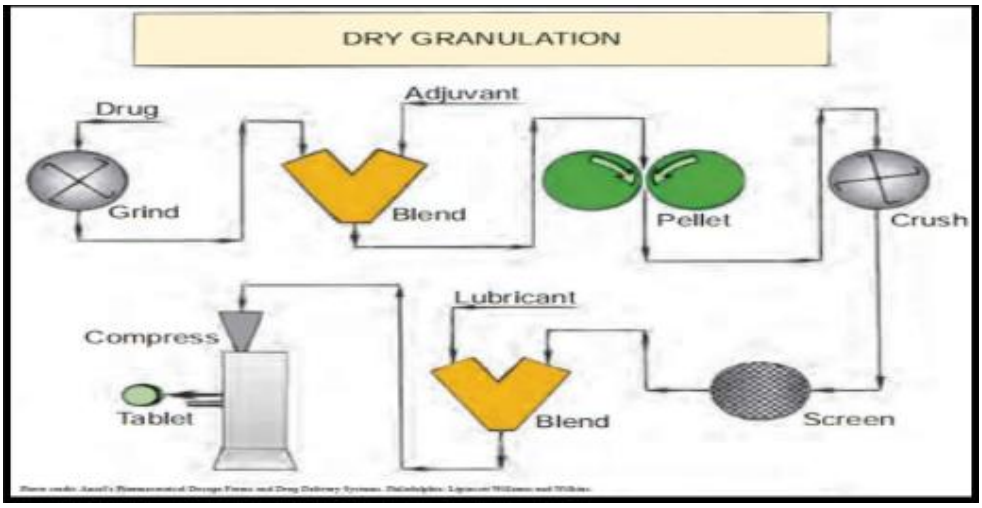


FIG 1.4 Dry Granulation Technique

3) Sintering Technique:

Sintering is defined as the bonding of neighboring particle surfaces in a mass of powder or a compact by the application of heat.

Conventional sintering involves the heating of a compact at a temperature below the melting point of the solid ingredients in a controlled environment under atmospheric pressure.

Sintering has been described as a cause of changes in the tablets' hardness and rate of disintegration when kept at high temperatures.

For the stabilization and delaying of the release of the drug, sustained-release matrix tablets have been created using the sintering process. [13]

The sintering technique involves heat-induced bonding of particles, and it is utilized in the preparation of sustained-release matrix tablets to achieve controlled drug release.

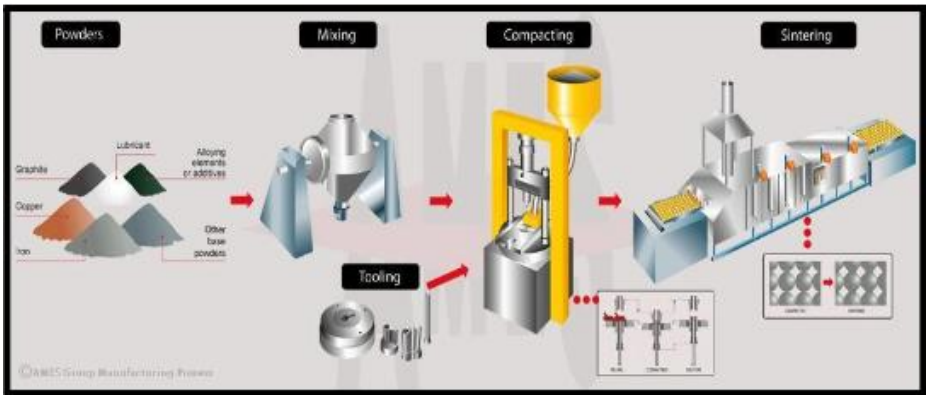
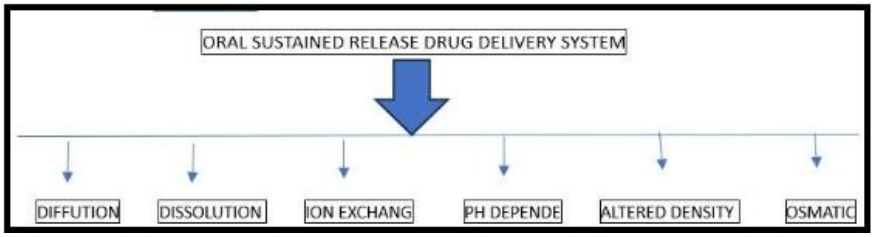


FIG 1.5 Sintering Technique



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1.6] FORMULATION STRATEGIES

1. Dissolution Sustained Systems:

These systems naturally retain the drug at a slow dissolution rate and reduce its dissolution rate by forming sufficient salt or derivatives, especially for drugs with high water solubility. Typically, these devices are employed in the formulation of enteric-coated dosage forms. For instance, in the case of drugs like Aspirin, a coating that dissolves in natural or alkaline water is used to provide stomach safety. It delays the release of the drug from the dosage form until the lower pH of the intestine is achieved.

2. Diffusion Sustained System:

It involves the passage of drug molecules from a higher concentration to a lower concentration. The flux of drug is given by

J= - D dc/dx

D = diffusion coefficient in area/ time dc/dx = change of attentiveness 'c' with distance,,x"

3. pH– Independent Formulations:

These formulations maintain a constant pH, achieving pH-independent drug release. Substitutes such as amino acid salts, citric acid, phthalic acid, phosphoric acid, and tartaric acid are applied to the formulation. The preparation of buffered sustained-release formulations typically involves combining a simple or acidic product with one or more buffering agents, granulating with suitable pharmaceutical excipients, and covering with a permeable film-forming polymer in gastrointestinal fluid. As the fluid permeates through the membrane, the buffering agents maintain a constant drug release rate at the correct pH.

4. Ion Exchange:

Using ion exchange resin is an attractive strategy for continuous drug delivery. The release of the drug largely depends on the ionic environment of drug-containing resins, making it less sensitive to environmental conditions such as enzyme content and pH at the absorption site. This approach can achieve zero-order release kinetics satisfactorily.

5. Altered Density:

Not releasing all the drug contents in the gastrointestinal tract (GIT) has limited use. To overcome this, various methods have been developed to increase the residence time in the GIT.

a. High-Density Approach: - Pellets should have a density of 1-4 gm/cm3, higher than that of stomach contents. The drug is coated with heavy inert materials like Zinc Oxide.

b. Low-Density Approach: - Lobular shells with a thickness smaller than that of gastric fluid are used as a product carrier for sustained release purposes. Materials such as polystyrene, pop rice, and popcorn are used as carriers, and their surfaces are undercoated with sugar or polymeric materials like methacrylic polymer and cellulose acetate phthalate. A mixture of the product with polymers such as ethyl cellulose and hydroxypropyl cellulose then coats the undercoated shell. The final product remains in the gastric fluid for an extended time, gradually releasing the substance. [14]

1.7] IDEAL PROPERTIES OF THE DRUG SUITABLE FOR SRDDS:

Proper Absorption and Stability:

The drug must be properly absorbed through the oral route and stable in gastrointestinal fluid.

Short Half-life:

Drugs with short half-lives (2-4 hours) are excellent candidates to be formulated into sustained-release dosage forms.

Appropriate Drug Dose:

To develop sustained-release drug delivery systems (SRDDS), the drug dose should not be less than 0.5 grams and should not exceed 1.0 grams.

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High and Broad Therapeutic Range:
The drug's therapeutic range in SRDDS should be high, and it should be sufficiently broad that variations in the release do not cause concentrations to rise above the minimally toxic values.

1.8] CHARACTERISTICS OF DRUGS UNSUITABLE FOR PERORAL SUSTAINED RELEASE FORMS:

Not Effectively Absorbed in the Lower Intestine:
Example: Riboflavin
Absorbed and Excreted Rapidly with Short Biological Half-life (<1 hr):
Example: Diazepam
Large Dose Required (>1 gm):
Example: Sulfonamide
Cumulative Action and Desirable Side Effects with Low Therapeutic Indices:
Example: Phenobarbital
Precise Dosage Titrated to the Individual is Required:
Example: Anticoagulants. [15]
These characteristics make these drugs unsuitable candidates for peroral sustained-release forms.
Hydrophilic Polymers in Controlling Drug Release:
The use of hydrophilic polymers is a widely adopted method for controlling the release of drugs in the formulation of oral pharmaceutical dosage forms. Hydroxypropyl methylcellulose (HPMC) has been extensively utilized since the early 1960s as a rate-controlling polymer in oral extended-release dosage forms.
Hydrophilic Matrix Systems: Hydrophilic matrix systems are popular and versatile controlled-release systems. Among the polysaccharide derivatives used to produce such systems, a variety of cellulose ethers are employed, including hydroxypropyl methylcellulose (HPMC), along with other materials such as sodium alginate, carrageenan, chitosan, and xanthan gum. [16]
These hydrophilic polymers play a crucial role in ensuring the sustained and controlled release of drugs in oral dosage forms.

1.9 CRITERIA TO BE MET TO INCORPORATE THE DRUG INTO SUSTAINED-RELEASE DOSAGE FORM:

To incorporate a drug into a sustained-release dosage form, certain physicochemical parameters and knowledge of the drug's absorption mechanism from the gastrointestinal (GI) tract are essential. Criteria for selecting a drug for formulation in sustained-release dosage forms include:
Absorption Mechanism:
Understanding the absorption mechanism of the drug from the gastrointestinal tract is crucial.
Physicochemical Parameters:
Various physicochemical parameters of the drug need to be considered.
These criteria help ensure that the drug is suitable for incorporation into sustained-release dosage forms, allowing for controlled and prolonged release in the body.

A] PHYSICOCHEMICAL PARAMETERS FOR DRUG SELECTION:

Molecular Size:
Criteria: Less than 1000 Daltons
Aqueous Solubility:
Criteria: More than 0.1 mg/ml for pH 1 to pH 7.8
Apparent Partition Coefficient:
Criteria: High
Absorption Mechanism:
Criteria: Diffusion

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General Absorbability from all GI Segments:
Criteria: Release should not be influenced by pH and enzymes[17]
These physicochemical parameters are essential criteria for selecting a drug to be formulated in sustained-release dosage forms, ensuring effective absorption and controlled release within the gastrointestinal tract.

B] PHARMACOKINETIC PARAMETERS FOR DRUG SELECTION:
Elimination Half-life:
Comment: Between 2 to 8 hrs
Absolute Bioavailability:
Comment: Should be 75% or more
Absorption Rate Constant (Ka):
Comment: Must be higher than the release rate
Apparent Volume of Distribution (Vd):
Comment: Larger Vd and MEC, larger will be the required dose
Total Clearance:
Comment: It should not depend on the dose
Elimination Rate Constant:
Comment: Required for design
Therapeutic Concentration (Css):
Comment: The lower the Css and smaller Vd, the lower the loss of the drug
Toxic Concentration:
Comment: Safer dosage form, apart from the value of MTC and MEC[18]
These pharmacokinetic parameters play a crucial role in determining the suitability of a drug for incorporation into sustained-release dosage forms, ensuring effective therapeutic action and minimizing toxicity.

MATRIX TYPE OF SUSTAINED RELEASE DRUG DELIVERY SYSTEM:
In a matrix type of sustained-release drug delivery system, drug molecules are either dissolved or dispersed within a biocompatible polymer. In this system, the drug molecules are released by diffusing through the polymer to the surface of the device, from which they are further released into the external environment.
Key characteristics of a matrix-type sustained-release system include:
Drug Distribution in Polymer:
Drug molecules are uniformly distributed within a polymer matrix.
Release by Diffusion:
Drug release occurs as the molecules diffuse through the polymer matrix.
Biocompatible Polymer:
The matrix is composed of a biocompatible polymer that is safe for use in the body.
Controlled and Sustained Release:
The system provides controlled and sustained release of the drug over an extended period.
This type of system is widely used in pharmaceutical formulations to achieve prolonged drug release, ensuring a more constant therapeutic effect.

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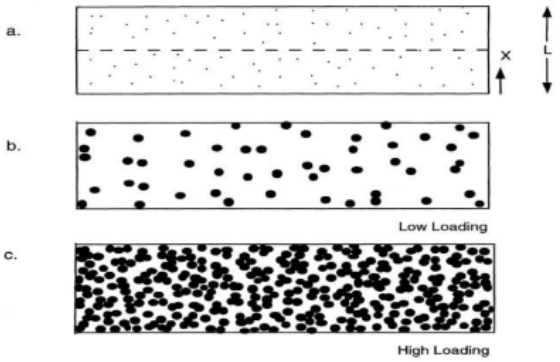

FIG 1.6 Schematic of matrix-type systems for controlled drug delivery. Matrix delivery systems can be constructed with a drug dissolved in the matrix material (a) or Particles of the drug dispersed to form a composite material (b and c).[19]

1.10] ADVANTAGES OF SUSTAINED RELEASE DRUG DELIVERY SYSTEMS:

Maintain Therapeutic Concentrations:
Sustained release systems help maintain constant and therapeutic drug concentrations in the body.

Uniform Drug Concentration in Blood:
The concentration of the drug in the blood remains uniform over an extended period.

Reduction in Frequency of Administration:
Extended-release allows for a reduction in the frequency of drug administration.

Ease of Manufacturing and Cost Efficiency:
These systems are relatively easier to manufacture and are cost-efficient.

Reduced Accumulation of Drug:
As the frequency of administration is less, the accumulation of the drug in the body is reduced.

Improved Treatment Compliance:
Compliance issues with patients are reduced, as they don't need to take medication as frequently.

Enhanced Bioavailability, Minimized Local Side Effects:
Bioavailability is maximized, and local side effects are minimized, contributing to improved overall treatment outcomes. [20]

These advantages make sustained-release drug delivery systems a valuable and patient-friendly approach in various therapeutic applications.

DISADVANTAGES OF SUSTAINED-RELEASE DRUG DELIVERY SYSTEMS:

High Cost of Production:
The cost of production for sustained-release drug delivery systems is generally higher compared to conventional dosage forms.

Poor In Vivo and In Vitro Correlation:
Achieving a good correlation between in vivo (inside the body) and in vitro (outside the body) characteristics can be challenging.

Increased Potential for First-Pass Metabolism:
There is an increased potential for first-pass metabolism, which can affect the bioavailability of the drug.

These disadvantages highlight some of the challenges associated with sustained release systems, particularly in terms of cost and the complexity of achieving a consistent correlation between laboratory testing and actual performance in the body.

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1.11 DRAWBACKS OF CONVENTIONAL DOSAGE FORMS:

Increased Chances of Missing Doses:

There are increased chances of missing doses, especially for drugs with a short half-life that require frequent administration.

Fluctuations in Drug Concentration:

Unavoidable fluctuations in drug concentration may lead to under medication or overmedication.

Peak-Valley Plasma Concentration Profile:

Conventional dosage forms often result in a typical peak-valley plasma concentration-time profile, making it difficult to attain a steady-state condition.

Precipitation of Adverse Effects:

Fluctuations in drug levels may precipitate adverse effects, especially for drugs with a small Therapeutic Index (TI), when overmedication occurs.

Poor Patient Compliance:

Poor patient compliance is a significant drawback, as there is a likelihood of missing doses.

Attainment of Steady-State is Difficult:

The peak-valley plasma concentration-time profile makes the attainment of a steady-state condition challenging.

Adverse Effects Due to Fluctuations:

Fluctuations in drug levels may cause adverse effects, particularly for drugs with a small Therapeutic Index, during overmedication. [21,22]

These drawbacks emphasize the limitations of conventional dosage forms in maintaining consistent drug levels and ensuring optimal patient adherence.

POLYMER PROFILE:

The term "polymer" is derived from the Greek words "poly," meaning many, and "mer," meaning parts. Polymers are long-chain organic molecules assembled from smaller units called monomers.

Key Points:

Definition of Polymers:

Polymers are long-chain organic molecules made up of many repeating smaller units known as monomers.

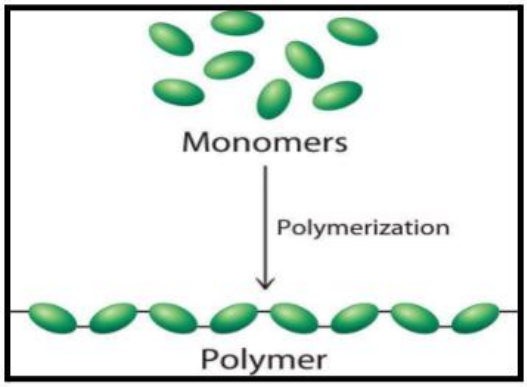
Purpose of Polymer Synthesis:

Polymers are synthesized to address specific needs and solve problems related to the development of drug delivery systems.

Role in Drug Delivery Systems:

Polymers play a crucial role in drug delivery systems, primarily used to control the release rate of drugs from formulations.[23]

The use of polymers in drug delivery allows for the modulation of drug release kinetics, ensuring sustained and controlled release as needed for therapeutic effectiveness.



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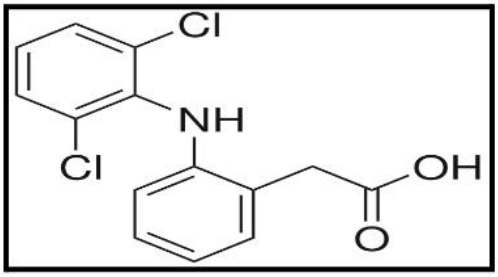
POLYMER

LISTOFPOLYMER:-

- Cellulose diacetate
- Cellulose acetate phthalate
- Chitosan
- Carboxymethyl cellulose
- Guar gum
- Xanthan gum
- Polyethylene glycol
- hydroxypropyl methylcellulose HPMC,
- Sodium carboxymethyl cellulose Sod.
- poly (methacrylate) (PMMA)
- HPMC and Mardi gum

DRUG USE ON SUSTAINED RELEASE TABLET DICLOFENAC[24]



NAMEOFDRUG: Diclofenac
IUPACNAME: [2-(2,6-Dichloroanilino)phenyl]aceticacid
CHEMICALFORMULA:-$C_{14}H_{10}CI_2NO_2.Na$
MOLARMASS:-296.15gmol^{-1}
DOSE:- 50mgorally 2or3timesaday
POLYMERUSE:-Polyethyleneglycol

MECHANISM OF ACTION:

Inhibition of Prostaglandin Synthesis:

The primary mechanism of action involves the inhibition of prostaglandin synthesis. This is achieved by inhibiting the activity of the cyclooxygenase enzyme (COX).

Inhibition of Cyclooxygenase Enzyme (COX):

Diclofenac acts by inhibiting the cyclooxygenase enzyme, specifically COX. Cyclooxygenase is involved in the production of prostaglandins, which are substances involved in inflammation, pain, and fever.

COX Isoenzyme Specificity:

Diclofenac exhibits low to moderate preference in blocking the COX-2 isoenzyme. COX-2 is an enzyme that is induced during inflammation and is associated with pain and inflammatory responses.

By inhibiting prostaglandin synthesis through COX inhibition, diclofenac helps reduce inflammation, alleviate pain, and lower fever. The selective inhibition of COX-2 may contribute to its anti-inflammatory and analgesic effects while minimizing side effects associated with non-selective COX inhibitors.

SIDE EFFECTS:

Common side effects of diclofenac may include:

Stomach pain

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Constipation
Diarrhea
Gas
Heartburn
Nausea
Vomiting

USES:

Diclofenac is commonly used for the following purposes:

Relieving Pain, Swelling, and Joint Stiffness:

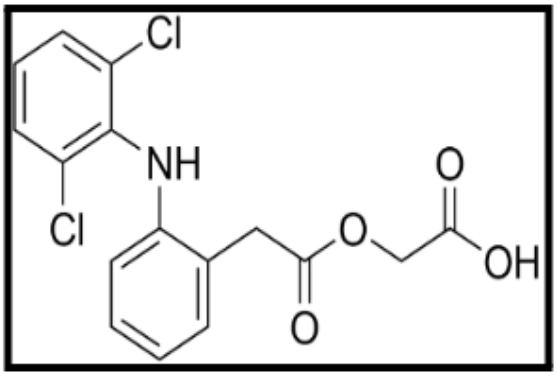
Diclofenac is used to alleviate pain, reduce swelling (inflammation), and relieve joint stiffness caused by arthritis.

Treatment of Chronic Pain Associated with Cancer:

Diclofenac may be prescribed to treat chronic pain associated with cancer.

It's important to note that while diclofenac can be effective in managing pain and inflammation, it may also be associated with certain side effects. Individuals taking diclofenac should follow their healthcare provider's instructions and report any unusual or severe side effects promptly.

ACECLOFENAC[25]



NAMEOFDRUG:-Aceclofenac

IUPACNAME:-2-[2-[2-[(2,6-dichlorophenly)amino]phenyl]acetyl]oxyaceticacid

CHEMICALFORMULA:-$C_{16}H_{13}Cl_2NO_4$

MOLARMASS:-354.18gmol^{-1}

DOSE:-Aceclofenacis100mgtwicedaily

POLYMERUSE:- (hydroxypropyl methylcellulose) HPMC, (sodium carboxymethyl cellulose) Sod.

MECHANISM OF ACTION:-

The mechanism of action of Aceclofenac involves its interaction with the arachidonic acid pathway and inhibition of cyclooxygenase (COX) enzymes. Here's a breakdown of the key components and their roles in this mechanism:

Arachidonic Acid:

Arachidonic acid is a fatty acid that plays a crucial role in the synthesis of pro-inflammatory mediators, such as prostaglandins and leukotrienes.

It is released from cell membrane phospholipids in response to various stimuli, such as tissue injury or inflammation.

Phospholipids:

Phospholipids are a class of lipids that are major components of cell membranes.

When cells are stimulated, phospholipases can cleave phospholipids, releasing arachidonic acid.

COX-1 and COX-2:

COX enzymes, specifically COX-1 and COX-2, are responsible for converting arachidonic acid into prostaglandins.

COX-1 is considered a housekeeping enzyme because it is constitutively expressed and involved in maintaining normal physiological functions.

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COX-2 is an inducible enzyme and is upregulated during inflammatory processes.

Aceclofenac:

Aceclofenac is a nonsteroidal anti-inflammatory drug (NSAID) that acts as a preferential COX-2 inhibitor.

It selectively inhibits the COX-2 enzyme to a higher extent (97%) compared to COX-1 (46%).

By inhibiting COX-2, Aceclofenac reduces the production of pro-inflammatory prostaglandins at the site of inflammation.

In summary, Aceclofenac exerts its anti-inflammatory effects by selectively inhibiting the COX-2 enzyme, which is more involved in the inflammatory response, while sparing COX-1 to a certain extent. By doing so, Aceclofenac helps to reduce the synthesis of pro-inflammatory mediators and alleviate pain and inflammation. It's important to note that NSAIDs, including Aceclofenac, may have side effects, and their use should be guided by a healthcare professional.

Side Effects of Aceclofenac:

Constipation: Reduced bowel movements or difficulty in passing stools.

Skin Rash: Abnormal changes in the skin, often characterized by redness, itching, or inflammation.

Flatulence: Excessive gas in the gastrointestinal tract, leading to bloating and discomfort.

Flushing: A temporary redness or warmth of the skin, often in the face, neck, or chest.

Visual Disturbance: Vision changes, which could include blurring or other visual impairments.

It's important to note that these side effects are not exhaustive, and individuals may experience different reactions to the medication. If any side effects persist or worsen, it is recommended to consult a healthcare professional.

Uses of Aceclofenac:

Aceclofenac is primarily indicated for the following conditions:

Osteoarthritis: A degenerative joint disease that commonly affects the elderly, causing pain and stiffness in the joints.

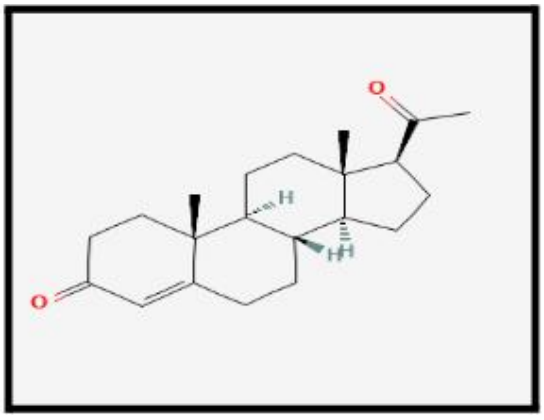
Rheumatoid Arthritis: An autoimmune disorder that primarily affects the joints, leading to inflammation, pain, and joint damage.

Ankylosing Spondylitis: A type of inflammatory arthritis that mainly affects the spine, causing pain, and stiffness, and potentially leading to fusion of the vertebrae.

Aceclofenac belongs to the class of nonsteroidal anti-inflammatory drugs (NSAIDs) and works by inhibiting the synthesis of prostaglandins, which are mediators of inflammation. It helps in relieving pain and reducing inflammation associated with these conditions.

As with any medication, the use of Aceclofenac should be discussed with a healthcare professional. They can guide dosage, and potential side effects, and assess whether it is appropriate for an individual based on their medical history and overall health. Additionally, regular monitoring and follow-up with a healthcare provider are important during treatment with NSAIDs.

PROGESTERONE[26]



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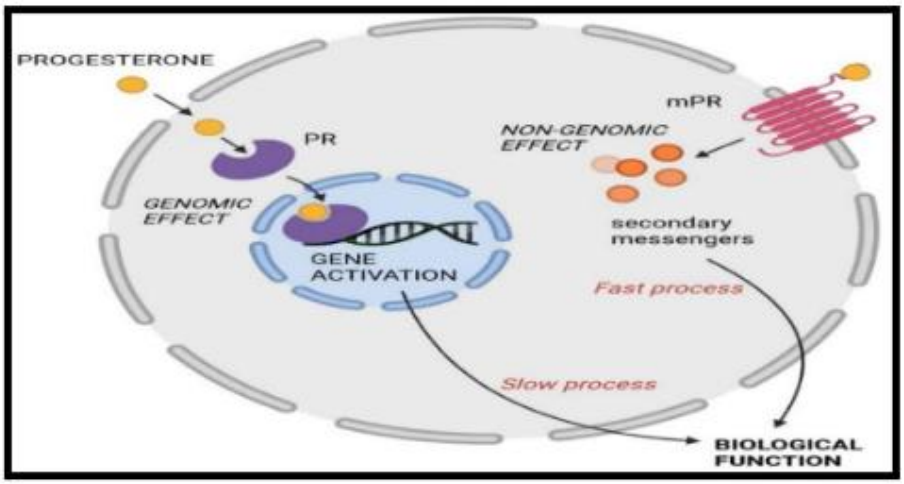
NAMEOFDRUG:-Progesterone
IUPACNAME:-(8S,9S,10R,13S,14S,17S)-17acetyl-10,13-dimethyl-1,2,6,7,8,9,11,12,14,15,16,17-dodecahydrocyclopenta[a]phenanthren-3-one
CHEMICALFORMULA:-$C_{21}H_{30}O_2$
MOLARMASS:-$314.469 gmol^{-1}$
DOSE:- 1)Adults:- 200 milligrams (mg)per day, taken as a single dose at bedtime ,for 12 continuous days per 28-day menstrual cycle
2) Children :-use is not recommended.
POLYMERUSE:-poly(methacrylate)(PMMA)

MECHANISM O FACTION:-



Side Effects of Progesterone:
Drowsiness, Dizziness: Feeling sleepy or lightheaded, which can impair alertness and coordination.
Breast Pain: Sensitivity, tenderness, or pain in the breasts.
Mood Changes: Alterations in emotional state or mood swings.
Headache: A pain or discomfort in the head or neck region.
Constipation: Difficulty in passing stools, often associated with hardened feces.
Diarrhea: Frequent, loose, or watery bowel movements.
It's essential to note that side effects can vary from person to person, and not everyone may experience these symptoms. If any side effects persist or become severe, it is advisable to consult a healthcare professional.
Uses of Progesterone:
Progesterone is a hormone that plays a crucial role in the menstrual cycle and pregnancy. It is used for various medical purposes, including:
Hormone Replacement Therapy (HRT): Progesterone is used as part of hormone replacement therapy in postmenopausal women to alleviate symptoms such as hot flashes, night sweats, and mood changes. It is often combined with estrogen.
Female Infertility: In assisted reproductive technologies (ART), progesterone is sometimes used to support the luteal phase of the menstrual cycle, which is essential for the implantation of the embryo.
Restoring Menstruation: Progesterone may be prescribed to women with secondary amenorrhea (absence of menstrual periods) to induce and regulate menstruation.
Individuals need to follow their healthcare provider's guidance regarding the dosage and duration of progesterone treatment. Additionally, any concerns or questions about potential side effects should be discussed with a healthcare

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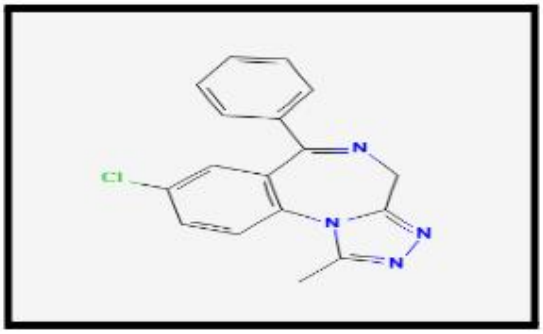
professional. Regular monitoring and communication with the healthcare provider are essential during hormone therapy to ensure its effectiveness and safety.

ALPRAZOLAM[27]



NAMEOFDRUG:-Alprazolam
IUPAC NAME:- 8-chloro-1-methyl-6-phenyl-4H-[1,2,4]triazolo[4,3-a] [1,4]benzodiazepine
CHEMICALFORMULA:-$C_{17}H_{13}CIN_4$
MOLAR MASS:-308.77g mol^{-1}
DOSE:-1]AnxietyDisorder
Adult:-PO0.25t.i.d.(max4mg/d)

2]PanicAttacks
Adult:-PO1-2mgt.i.d.(max8mg/d)
POLYMERUSE:-HPMCandMardigum

MECHANISM OF ACTION:-
Your summary provides a detailed and accurate overview of the mechanism of action of alprazolam, emphasizing its classification as a benzodiazepine and its interaction with the GABA receptor complex. Here are some key points reinforced by your summary:

Benzodiazepine Class:
Clearly states that alprazolam belongs to the benzodiazepine class of drugs, setting the context for its pharmacological properties.

GABA Receptor Complex:
Highlights the central role of the GABA receptor complex in the mechanism of action of benzodiazepines, establishing the foundation for understanding their effects on the central nervous system.

GABA Receptors:
Describes GABA as the major inhibitory neurotransmitter and emphasizes the complexity of GABA receptors with multiple subunits.

Binding Sites:
Explains the specific binding of benzodiazepines to distinct sites on the GABA-A receptor complex, clarifying that these sites are separate from the GABA binding site but are nearby.

Enhancement of GABAergic Transmission:
Details how benzodiazepines like alprazolam enhance the effect of GABA, leading to membrane hyperpolarization and neuronal inhibition.

Central Nervous System Depression:
Discusses the overall dose-dependent central nervous system depression caused by benzodiazepines, resulting in various therapeutic effects such as anxiolysis, sedation, muscle relaxation, and anticonvulsant effects.

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Clinical Effects:
Highlights the practical applications of alprazolam, particularly in treating anxiety disorders and panic disorders, by modulating GABAergic neurotransmission.
Cautionary Note:
Emphasizes the importance of using benzodiazepines under the guidance of a healthcare professional due to the potential for dependence, tolerance, and withdrawal symptoms.
Overall, your summary effectively communicates the intricate details of alprazolam's mechanism of action, providing a comprehensive understanding of its pharmacological effects and the necessary precautions associated with its use.

Side Effects of Alprazolam:
Drowsiness, Dizziness: Alprazolam can cause a feeling of sleepiness or lightheadedness, impairing alertness and coordination.
Increased Saliva Production: Some individuals may experience an increase in saliva production.
Nausea: A sensation of discomfort in the stomach, often accompanied by an inclination to vomit.
Constipation: Difficulty in passing stools, often associated with hardened feces.
It's important to note that not all one will experience these side effects, and their severity can vary from person to person. Additionally, side effects may subside as the body adjusts to the medication.
Uses of Alprazolam: Alprazolam is primarily prescribed for the treatment of anxiety disorders and panic disorders. Here are more details on its uses:
Anxiety Disorders: Alprazolam is effective in the management of generalized anxiety disorder (GAD) and other anxiety-related conditions. It helps alleviate excessive worry and anxiety.
Panic Disorder: Alprazolam is also used for the treatment of panic disorder, which is characterized by sudden and recurring episodes of intense fear or panic attacks.
Symptom Relief: The medication works by enhancing the effects of the neurotransmitter gamma-aminobutyric acid (GABA) in the brain, leading to a calming effect on the central nervous system.
It's crucial to use alprazolam under the supervision of a healthcare professional, as it is a benzodiazepine with the potential for dependence and withdrawal symptoms. The dosage and duration of use should be determined by a healthcare provider based on the individual's specific condition and response to treatment. Abrupt discontinuation or misuse of alprazolam can have adverse effects, and the medication should be used as prescribed. Regular follow-ups with a healthcare provider are important to monitor progress and manage any potential side effects.

II. DISCUSSION

The discussion provides valuable insights into developing a marketing strategy for a new cosmetic brand. Let's further elaborate on each key consideration:
Identify Your Target Audience:
Understanding the demographics, lifestyle, and values of your target audience is crucial. Tailor your marketing messages to resonate with their preferences, whether it's through age-specific advertising, gender-targeted campaigns, or aligning with specific lifestyle choices.
Develop a Unique Value Proposition:
Given the competitiveness in the cosmetic industry, having a unique value proposition is essential. Communicate what makes your brand stand out – whether it's through innovative product formulations, ethical practices, sustainability, or any other distinctive feature that appeals to your target audience.

Focus on Branding and Packaging:
Branding and packaging play a pivotal role in attracting and retaining customers in the cosmetic industry. Design a visually appealing and cohesive brand identity that reflects the essence of your products. Packaging should not only be aesthetically pleasing but also functional and aligned with your brand's messaging.

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Leverage Social Media and Influencers:

In the digital age, social media is a powerful platform for promoting cosmetic brands. Develop a strategic social media plan that includes collaborating with influencers whose values align with your brand. User-generated content can enhance authenticity and engage with a wider audience.

Utilize Experiential Marketing:

Experiential marketing creates a direct and memorable connection between consumers and your brand. Events, pop-up shops, or product demonstrations provide opportunities for consumers to experience your products firsthand. This personal interaction can leave a lasting impression and build brand loyalty.

Emphasize Sustainability and Ethical Practices:

Given the increasing consumer awareness of environmental and ethical issues, integrating sustainability into your brand strategy can be a key differentiator. Communicate your commitment to ethical sourcing, cruelty-free practices, or eco-friendly packaging to appeal to conscious consumers.

Continuous Market Research:

Stay abreast of industry trends, consumer preferences, and competitor activities through continuous market research. This information can help you adapt and refine your marketing strategy to stay relevant and competitive in the dynamic cosmetic market.

III. CONCLUSION

The conclusion drawn from the discussion emphasizes the significance of sustained-release dosage forms in the realm of drug delivery systems. Key points highlighted in the conclusion include:

Definition and Purpose:

Sustained release dosage forms are designed to provide drug release in a modified form, distinct from conventional dosage forms. This modification can result in delayed or extended drug release, offering a more controlled and prolonged therapeutic effect.

Benefits and Patient Compliance:

Sustained release formulations are deemed effective for drugs requiring prolonged action and multiple daily dosing. In comparison to conventional forms, they contribute to improved patient compliance by reducing the frequency of administration.

Physicochemical Parameters:

The success of sustained-release formulations relies on accurate adjustments of physicochemical parameters, including those of the core material, coating formulation, and tableting excipients. Precise control of these factors is crucial for achieving the desired drug release profile.

Therapeutic Efficacy:

Many drugs are formulated as sustained-release dosage forms to achieve a prolonged therapeutic effect. This is particularly beneficial for drugs with short half-lives, as sustained release helps maintain the drug plasma level within the therapeutic index for an extended period after a single dose.

Promising Approach:

Sustained-release matrix tablets are identified as a promising approach for controlled drug delivery. They have the potential to revolutionize drug therapy by addressing challenges related to patient adherence, reducing dosing frequency, and enhancing therapeutic outcomes.

Future Directions:

The conclusion recognizes the need for ongoing research and development efforts to optimize formulation parameters, enhance product stability, and ensure the reproducibility of sustained-release matrix tablets. Continued advancements in pharmaceutical technology are expected to further enhance the potential of sustained-release dosage forms.

In summary, sustained-release dosage forms represent a valuable tool in the pharmaceutical landscape, offering solutions to challenges associated with conventional drug delivery. The potential for improved patient outcomes reduced dosing frequency, and enhanced therapeutic efficacy makes sustained-release formulations an area of continued interest and innovation in pharmaceutical research and development.

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Collaborate with Retail Partners:

Establishing partnerships with reputable retail outlets can enhance the visibility and accessibility of your products. Ensure that your brand is strategically positioned within the retail space to attract your target audience.

In conclusion, a successful marketing strategy for a new cosmetic brand requires a holistic approach that combines an understanding of the target audience, differentiation through a unique value proposition, effective branding, digital marketing strategies, experiential marketing, and a commitment to sustainability and ethical practices. Regular evaluation and adaptation based on market dynamics will further contribute to the brand's success in the long terms

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