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Natural Gums Used as Binder in Sustained Release Preparation

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ABSTRACT

***Background**: The main idea behind a sustain-release system is to enhance the effectiveness of the medicine while minimizing side effects. Sustain-release preparations are designed to release medication at a predetermined time rate, minimizing side effects and maintaining a steady concentration over a specified period of time. To achieve the sustained effect, techniques such as polymer swelling, water penetration, drug dissolution and diffusion have been employed to facilitate drug release through a matrix system. Compared to traditional release formulations, advancements in formulation technology, including sustained release systems, have been widely accepted. Naturally occurring plant-based gums can be used for sustained release formulations due to their excellent binding properties.*

***Methods**: Articles were retrieved from Science-Direct, Google Scholar, PubMed and other online sources. Important keywords like "gums,'' "binders", and "sustained release'' were used to examine important literature relevant to the study from these databases.*

***Results**: The results provide a concise overview of different formulation strategies for enhancing sustained delivery systems, along with the required materials, their corresponding applications, and the plant families they belong to.*

***Conclusions**: An insight into some natural gums used as binders in sustained release preparation has been revealed, highlighting their importance in reducing the frequency of administration and improving patient compliance. However, the utilization of indigenous materials in formulations can help lower the market value of the pharmaceutical product.*

***Keywords**: Gum, sustained release, Binders, Diffusion, Dissolution, Granulation.*

Introduction

The verifiable evolution of drug delivery systems highlights the progression from simple formulations to sophisticated, technology-driven approaches. Sustained release preparations offer numerous advantages over the conventional forms. The main objective of a sustained release dosage form is to maintain blood drug levels at a stable, non-toxic and therapeutically effective concentration over an extended period of time.[1] A key component in achieving this objective is the development of appropriate dose schedules. Drug therapy that aims for prolonged therapeutic effects by continuously releasing medication over an extended period following a single dose administration is known as sustained release.[2] Before 1950, most drugs were formulated as pills or capsules that released the loaded drug immediately upon contact with water, without any ability to control the drug release kinetics.[3]

The advantages they offer, along with demand in the pharmaceutical market, make sustained-release formulations a popular oral dosage form.[4]

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The origin of pharmaceutical drug delivery systems can be traced back to the 1938 patent who coated pellets for extended release.[5] The system tends to keep constant drug levels in the target tissues.[6]

With pharmaceutical companies increasingly adopting advanced drug delivery systems to prolong market life and revenue potential of their major products, while also addressing the needs of the growing elderly population that requires convenient and effective therapies, it is not surprising that the oral drug delivery market has grown into a $35 billion industry. The market is expected to expand by up to 10 % annually, thereby increasing the popularity of formulations such as sustained-release systems.[7] The extremely high cost of developing new drug molecules has led pharmaceutical companies to explore various strategies for advancing new drug delivery systems.[8]

Excipients are substances other than the Active Pharmaceutical Ingredients (API) that have been evaluated for safety and are intentionally included in the drug delivery system, where they play a crucial role.[9] Most excipients are derived from natural products. A natural product is a chemical compound produced by a living organism, such as a plant, animal, fungus or microorganism.[10] Excipients can be classified based on their source, such as plant, animal, mineral or synthetic origins or according to their function in the formulation, like the binders, glidants, lubricants, fillers, sweeteners and coating agents.[11] Several pharmaceutical gums can be used in sustained release formulations, as most of them have the ability to swell in water and form a matrix that gradually releases the active drug over time.[12]

Sustained-release systems employ both physical and chemical principles, as the primary objective of these formulations is to reduce the dosing frequency and enhance drug effectiveness by maintaining or localizing the drug at the desired site of action[13].

Significant advancement has been made to address the limitations of conventional dosage formulations, thereby improving drug bioavailability and reducing the frequency of overall dosing.

Advantages

a. Improved efficiency in treatment: Ideal therapy of a disease requires a well-organised delivery of active drugs to the tissues and organs that need treatment, and if not achieved, may lead to undesirable, toxicological and immunological effects in non-target tissue. Sustained-release dosage forms haver proven to provide better management of both acute and chronic disease conditions.[14]

b. Patient Compliance: Lack of adherence is generally observed with long term treatment of chronic diseases, as the success of drug therapy depends upon the ability of the patient to adhere to the regimen schedules.[15] Patient conformity is affected by a combination of many factors, like having consciousness of the disease process, religious beliefs in therapy and the sensitivity of the need to follow a strict treatment schedule. Patients generally prefer taking medications that require less frequent dosing.[16]

c. Reduced total dose: Sustained release systems have been shown to require a lower total amount of drug in treatment of disease conditions.[17] By reducing the total amount of drug administered, there is a corresponding decrease in both systemic and local effects, with overall greater economic benefit.

d. Reduced fluctuation: Administration of a drug in a conventional dosage form often results in fluctuating drug concentrations within the systemic circulation and tissue compartments.[18] The magnitudes of these fluctuations depend on the pharmacokinetic parameters such as the rate of absorption, distribution, metabolism, elimination and dosing intervals. The valley pattern is more pronounced in drugs with biological half-lives of less than 4 hours, as prescribed dosing intervals are seldom shorter than 4 hours.

e. Economic perspective: Although, extended release (ER) medications have not consistently shown therapeutic or adherence superiority and switching these medications to some less expensive generic immediate formulations may offer an opportunity to reduce care cost,[19] but on the frequency of getting or purchasing the medications, it tends to reduce on the part of the patient because of the long lasting effect on the system leading to overall cost reduction since controlled release formulations (SRF) can be used to reduce the amount of drug necessary to cause the same therapeutic effects in patients.[20]

Drug Selection

The evaluation of biopharmaceuticals is critical in the formulation of a sustained release (SR) preparation. The mechanism of absorption of the dosage form from the gastrointestinal tract, along with pH and Solubility profile, are key factor in designing and formulating a preparation. The Biopharmaceutical classification system depends on the solubility, dissolution and intestinal permeability. In 2007, Aulton explained the characteristics that make a drug suitable for sustained release formulation, and they include:[21]

a. Long elimination half-life: Long elimination mostly above 2 hrs (h) will favour SRF.

b. Short elimination half-life: Moderate elimination of drugs below 8 h will favour SRF

c. Broad therapeutic index: Prolonged exposure to drugs may result in sensitisation or tolerance, thereby altering the relationship between drug concentration and therapeutic effect.[22] Variation in parameters needs to be accounted for during formulation, and a broad therapeutic action could help in this instance. Drugs with a low therapeutic index are generally not suitable for the formulation into sustained-release preparations.

d. Good absorption window

Sustained-release formulations are designed to release at a steady rate for a particular period of time. Certain drugs, when administered orally, can be absorbed only from a specific part of the GIT. This type of medication presents challenges when formulating it into a sustained release system.[23]

e. Poor first-pass clearance: A low first-pass effect favours the development of sustained release formulations, as the drug is less likely to be extensively inactivated by enzymatic metabolism.

f. Small doses: High doses in conventional formulations present a challenge for sustained-release systems, as the resulting unit dose may become too large to administer conveniently.

Formulation strategies involve sustained release preparation

Dissolution-controlled-release sustained-release

In this mechanism, oral formulations utilize dissolution as the time-limiting step in drug release. For example, if a drug dissolves rapidly, it can be incorporated into a tablet containing a carrier that has a slower dissolution rate. In this scenario, Noyes-Whitney, describe the dissolution process at steady rate by the equation below:

$$\frac{dc}{dt} = \text{KDA (Cs-C)} \text{ ---------- (1)}$$

Where, $\frac{dc}{dt}$ = Dissolution rate

C = Concentration from the bulk

Cs =Saturated Solubility denoted

Dissolution-controlled formulations are categorised into matrix dissolution systems and encapsulation dissolution systems.

Using a slow-dissolving polymer, as illustrated in Figure 1, individual particles or granules can be coated to form an encapsulated reservoir system.[24]

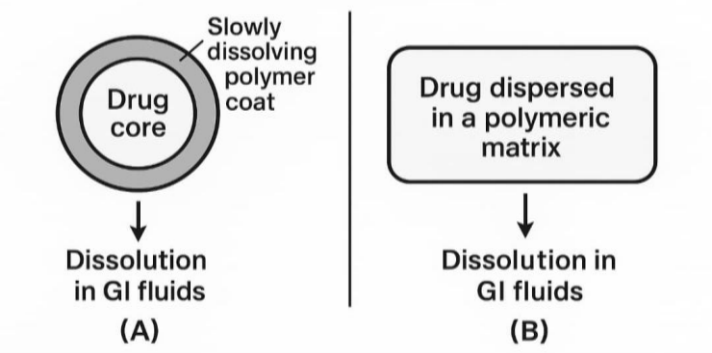

Figure 1: Schematic representation of dissolution-controlled release systems[25]

Diffusion-controlled release

In diffusion-controlled release models, the limiting step is the diffusion of dissolved drug through a polymeric material. The drug release system rate will not follow the zero-order kinetics because the diffusion path length increases with time as the drug in the matrix becomes reduced.[26] The drug release characteristics of a sustained-release preparation via diffusion are shown in Figure 2.

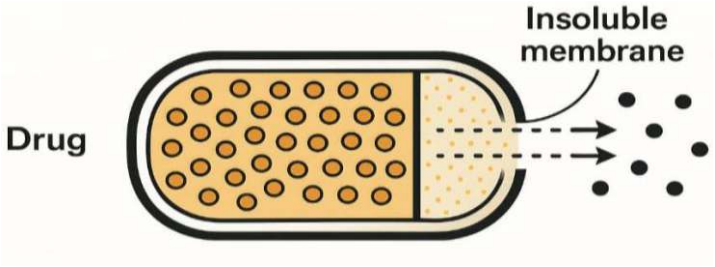

Figure 2: Drug release of diffusion across the insoluble membrane of the reservoir device[27]

The mechanism involved in the diffusion process shows the movement of drug molecules from a region of a higher concentration to a region of lower concentration.[28]

The drug release rate is $\frac{dm}{dt}$ = ADK∧ C/L ---------- (2).

Where A = Area

K = Partition coefficient of drug between the membrane and drug core

L = Path length of the diffusion process

∧C = Difference in concentration across the membrane

Combined Diffusion and Dissolution Controlled Release Systems

In this system-controlled release system, the drug is enclosed in a membrane that is partially water-soluble.[29] The dissolution of the membrane occurs due to the formation of pores, which subsequently allow the aqueous medium to penetrate the membrane, as seen in a novel system using ethyl cellulose with methyl cellulose, can be seen shown in Figure 3 below:

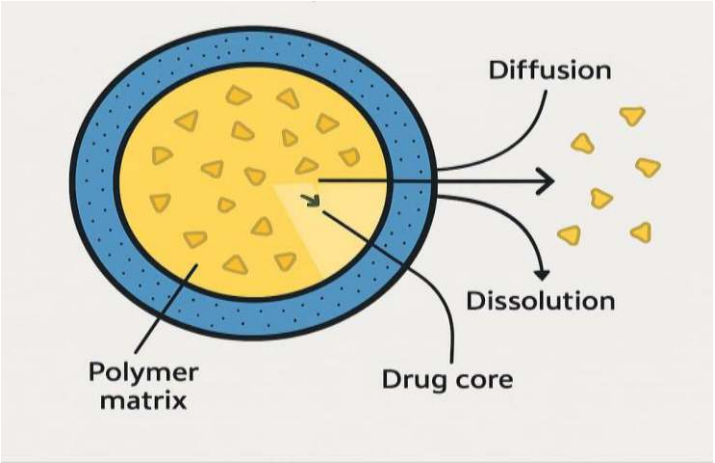

Figure 3: Drug release of combined diffusion and dissolution across the insoluble membrane[8]

pH-dependent control systems

Agents that resist a change in pH are used in this unique mechanism of sustained release formulation. Some notable drugs, after undergoing dissolution and absorption in the gastrointestinal tract (GIT), can alter the pH of the medium. To prevent this, a permeable coating is used to allow selective entry of the medium while preventing tablet dispersion.[30]

Incorporation of functional polymers like pH – sensitive properties group into pharmaceutical dosage form is an essential technique in designing novel formulations with sustain release preparation.[31]

A prototype pH-dependent sustained release system is shown schematically in Figure 4

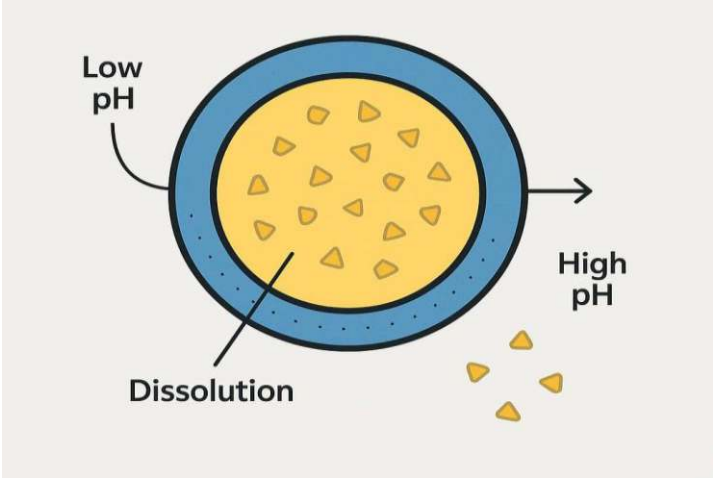

Figure 4: A pH-dependent mechanism in sustained release preparation[32]

Osmotic pressure systems are controlled

In an oros-controlled system, the drug is released at a constant zero-order kinetics. In this system, drugs and osmotic agents like potassium Chloride (KCL) are contained in the reservoir. The release of the drug from the reservoir is not affected by the condition of the GIT, but factors like the size of the orifice, osmotic properties of the inner layer and thickness of the membrane.[33] Figure 5 below shows the osmotic-controlled release systems as depicted:

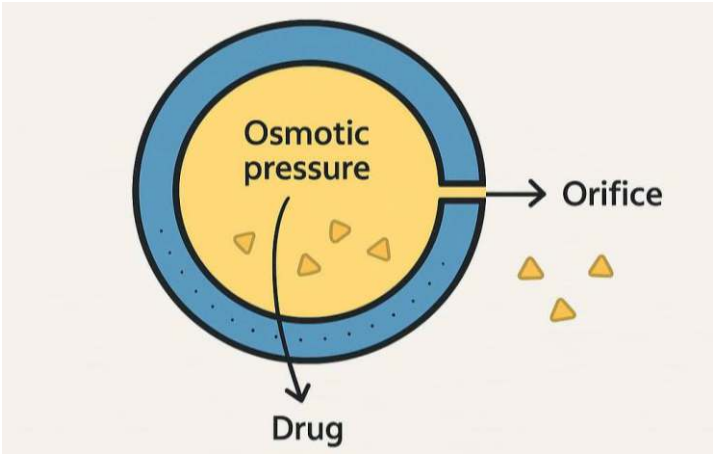

Figure 5: Osmotic system control in sustained release system[34]

Ion exchange sustained release systems

Most resins generally contain anionic groups such as quaternary ammonium groups and cationic groups like carboxylic group forming a complex with drugs. Some drugs form complexes that undergo exchange within the gastrointestinal tract and subsequently released in the presence of sufficient Na^+ and Cl^- present in the tract.[35]

Ion exchange resins drug complexes are effectively used in sustained release preparations by exploiting the resin's ability to control the release rate of the drug through ionic interaction, as shown in Figure 6 below:

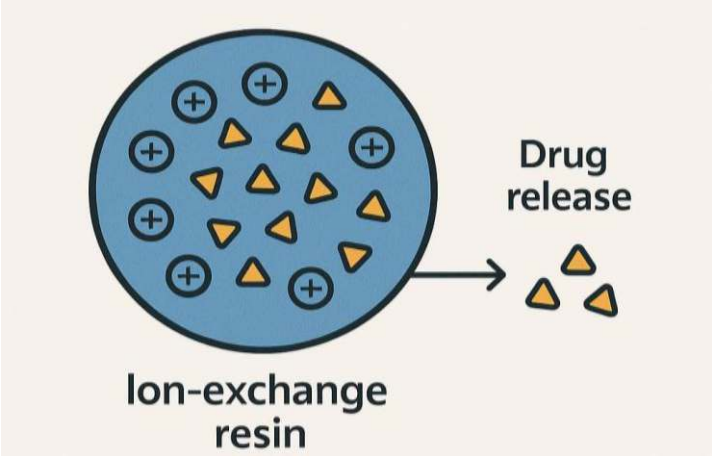

Figure 6: Ion exchange system in sustained release preparation[36]

Pharmaceutical Binders for Sustained Release Formulation

To ensure tablet cohesiveness, binders are incorporated during formulation.[37] This ensures the tablet remains intact after the compression process. Polymers of plant origin are gaining increasing importance because of their wide range of pharmaceutical applications, such as diluents, binders, and disintegrants. Gums and mucilage, which are abundantly found in various plants with diverse structures and metabolic functions.[38] Some notable gums and mucilage used as tablet binders are shown in Table 1 below:

Table 1: Some common gum use in pharmaceutical formulation

S/No	Common name	Botanical name	Family
1	Gum Acacia	*Acacia catechu*	Leguminosae
2	Gum Albizia	*Albiziazygia*	Leguminosae
3	Gum Khaya	*Sterculianurens*	Sterculiaceae
4	Gum Neem	*Azadirachta indica*	Meliaceae
5	Gum Tragacanth	*Astragalus gummifer*	Leguminosae
6	Gum Xanthum	*Xanthomonas lempestris*	Xanthomonadaceae
7	Gum Cashew	*Anacardium occidentalle*	Anacadiaceae
8	Gum Moringa	*Moringa oleifera*	Moringaceae
9	Gum Okaro	*Abelmoschus esculentus*	Malvaceace
10	Gum Almond	*Prunnus communis*	Rosaceae

The natural excipients possess several advantages over the synthetic counterparts as they are non-toxic, cost effective and readily available.[39] Natural gums can be modified to suit the specific requirements of a drug delivery system, allowing them to compete with synthetic excipients available on the market.[40] The use of plants as excipients in drug formulation and development is highly desirable, as they are generally regarded as safe (GRAS). In addition, plants are cheap, biocompatible and readily available.

Plant-derived gums are polysaccharides obtained from various plants sources: some of these have been used medicinally for centuries, as documented by Theophrastus in the 3rd century BC.[41]

They have the potential to bind water and form gels and are regularly linked with proteins and minerals in their structure.[42] Gums exist in different forms, such as mucilage gums, exudate gums, seed gums, and others etc. Plant-derived gums have been widely used by humans since ancient times for numerous applications.[43] Extensive use of some of these plant materials as binders can alter the physicochemical properties of the final formulation by adjusting its pharmacokinetic properties.[44] Frequently used gums for pharmaceutical formulations are shown in Figure 7 below.

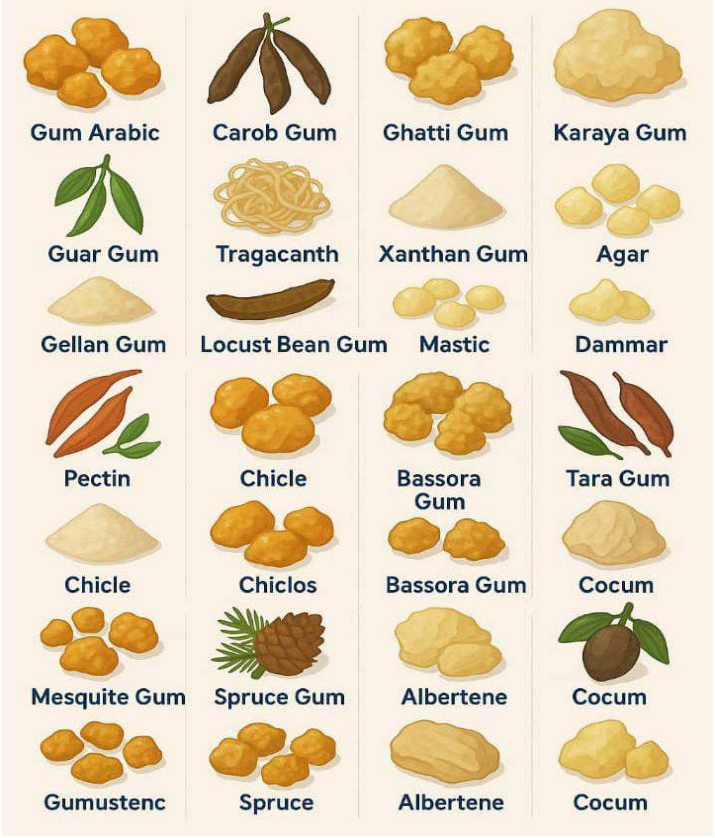

Figure 7: Some known gums that are widely used in sustained release preparations[45]

Gum tragacanth is one of the most widely used gums employed in previous studies. In combination with several others are listed in Figure 7 and Table 2, along with their respective pharmaceutical applications.

Table 2: Gums and their pharmaceutical applications

S/No	Common Name	Structure	Application
A	Tragacanth	Xylogalacturonans Pectinaceous	Sustain release Suspending agent
B	Guar gum	Galactose	Controlled drug delivery Sustain release
C	Grewia gum	Glucose Rhamnose	In-vitro Drug release Binding property
D	Okra gum	Xylose Galactose Arabinose	Controlled release tablets Sustained released Suspending agents
E	Moringa gum	Glucoronic acid Rhamnose	Gelling agents Binding agent
F	Olibanum gum	Resin acids Boswellic acid Oil content	Binding agent Disintegrating
G	Locust bean gum	Pentane Proteins Cellulose	Super-disintegrant Controlled drug delivery Drug targeting to the colon

Preparation

Sustained-release matrix tablets can be prepared in two ways:

a. Direct compression: This involves the compression of the powder blend comprising the drug, polymer and other excipients. Direct compression is preferably used in tablet manufacturing.[46]

b. Granulation: Granulation is carried out prior to the compression process. [47] Pharmaceutical granules range between 0.2 and 4 mm and are agglomerates of powder particles that are formed to improve flow properties,

compressibility, and uniformity of a formulation before further processing, such as tablet compression or capsule filling.[48] Bonds are formed by compression or by using a binding agent.[49] Selection of the ideal method depends on the properties of the drug, polymer and other ingredients. Granulation is the process of particle enlargement by the agglomeration technique, which is the most significant unit operation in the production of tablets and capsules.[50]

Conclusion

Sustained-release systems represent a significant advancement in drug delivery technology, offering numerous benefits such as improved patient compliance, consistent plasma drug concentrations and reduced dosing frequency.

Continued research and Innovation in material science, formulation techniques, and biological targeting are expected to further sustained release systems, making them an essential component of future pharmaceutical development.

A large number of naturally occurring polymers, such as gums and mucilage, serve as binding agents in pharmaceutical formulations for sustained-release. Several plant species have been utilised as binding agents and drug excipients.

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