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Formulation and Evaluation Of Sustained Release Tablets Using Natural Polymers

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ABSTRACT

Sustained release formulations play a vital role in maintaining consistent plasma drug concentrations over extended periods, thereby reducing dosing frequency and improving patient compliance. This study focuses on the formulation of sustained release tablets using natural polymers such as guar gum, xanthan gum, and chitosan. These biopolymers offer biodegradability, biocompatibility, and economic advantages compared to synthetic polymers. Wet granulation was employed to prepare the tablets, followed by evaluation of pre- and post-compression parameters, including hardness, friability, weight variation, and dissolution rate. In-vitro release studies demonstrated that polymer concentration significantly influenced drug release kinetics, conforming to Higuchi and Korsmeyer–Peppas models. Natural polymers proved effective in achieving controlled release profiles while ensuring the stability and integrity of the dosage form.

KEYWORDS: *Sustained release, Natural polymers, Drug release kinetics, Biopolymers, Tablet formulation*

INTRODUCTION

Sustained release tablets (SR tablets) are designed to release drug in a controlled manner over an extended period, reducing dosing frequency, enhancing patient compliance, and maintaining therapeutic drug concentration in plasma. Conventional immediate-release dosage forms often cause fluctuations in plasma drug concentration, which can lead to sub-

therapeutic or toxic levels. Therefore, the development of sustained or controlled release dosage forms is of great importance in modern pharmaceutics.

Natural polymers have gained significant attention in pharmaceutical technology due to their biocompatibility, biodegradability, non-toxicity, and availability from renewable sources. They can act as matrix formers, binders, gelling agents, or release retardants in sustained release systems. Some commonly used natural polymers include guar gum, xanthan gum, karaya gum, chitosan, alginates, and starch derivatives. These polymers provide the advantage of modulating drug release through swelling, erosion, or diffusion mechanisms, depending on their physicochemical properties and interaction with the drug.

Table 1: Common Natural Polymers Used in Sustained Release Tablets

Polymer	**Source**	**Drug Release Mechanism**	**Advantages**
Guar gum	Seed of Cyamopsis tetragonoloba	Swelling/ Diffusion	Biodegradable, good swelling
Xanthan gum	Fermentation of sugars	Swelling/ Diffusion	High viscosity, stable
Chitosan	Chitin (crustacean shells)	Erosion/ Diffusion	Biocompatible, biodegradable
Karaya gum	Sterculia trees	Swelling/ Erosion	Natural, good gelling
Alginates	Brown seaweed	Gel formation/ Diffusion	pH sensitive, good gel strength

LITERATURE REVIEW

Several studies have been conducted on the use of natural polymers in sustained release formulations. Singh et al. (2018) reported that guar gum effectively controlled the release of metformin hydrochloride over 12 hours, exhibiting a diffusion-controlled release mechanism. Similarly, Patel and Mehta (2019) demonstrated the use of xanthan gum in matrix tablets of diclofenac sodium, achieving a prolonged drug release pattern without compromising tablet integrity.

Chitosan, a cationic polymer obtained from chitin, has been extensively investigated for

sustained release of water-soluble drugs. Its ability to form hydrophilic matrices and interact electrostatically with anionic drugs allows controlled drug release by modulating swelling and erosion rates. A study by Kumar et al. (2020) showed that chitosan matrices of propranolol hydrochloride could sustain release up to 24 hours with minimal burst effect.

Alginates and karaya gum are another class of natural polymers frequently used for matrix tablets. Alginates, obtained from brown seaweed, form gels in the presence of divalent cations like calcium, providing a diffusion barrier for drug release. Karaya gum exhibits excellent swelling properties, which prolong drug release, making it suitable for hydrophilic drugs. Several research reports have indicated that combinations of natural polymers may produce synergistic effects, enhancing both drug release control and mechanical properties of tablets.

ADVANTAGES OF USING NATURAL POLYMERS

Natural polymers, derived from plants, animals, or microbial sources, have increasingly gained attention in pharmaceutical formulations, particularly in sustained or controlled release drug delivery systems. Their unique physicochemical and biological properties make them highly suitable for developing safe, effective, and patient-friendly formulations. The major advantages are as follows:

1. Biodegradability

One of the most significant benefits of natural polymers is their inherent biodegradability. These polymers can be broken down by natural enzymatic or hydrolytic processes within the body into harmless by-products. For example, polysaccharides like chitosan and alginate degrade into sugars, while proteins such as gelatin and albumin are metabolized into amino acids. This property ensures that the polymer carrier does not accumulate in the body, reducing the risk of long-term toxicity or adverse effects. Biodegradability also eliminates the need for surgical removal of the delivery system, which is often required for non-degradable synthetic polymers.

2. Biocompatibility

Natural polymers generally exhibit excellent biocompatibility, meaning they interact favorably with biological tissues without eliciting significant immune responses. This reduces the risk of inflammation, allergic reactions, or irritation, making them suitable for sensitive

routes of administration such as transdermal, ocular, or parenteral delivery. For instance, hyaluronic acid and cellulose derivatives are well-tolerated by the body and have minimal immunogenicity, which enhances patient safety and compliance.

3. Cost-effectiveness

Many natural polymers are abundantly available and sourced from renewable biological materials, such as plant gums, starches, or microbial exopolysaccharides. This widespread availability makes them economically attractive compared to synthetic polymers that often require complex chemical synthesis. The use of natural polymers reduces raw material costs, simplifies the production process, and contributes to environmentally sustainable manufacturing practices.

4. Versatility

Natural polymers are highly versatile in pharmaceutical applications. They can be chemically or physically modified to tailor their mechanical strength, solubility, or degradation rate, which in turn controls the drug release profile. For example, crosslinking alginate with calcium ions forms a hydrogel that can sustain drug release over hours to days. Similarly, blending different polymers allows formulators to achieve desired characteristics such as mucoadhesion, pH sensitivity, or controlled swelling. This adaptability makes natural polymers suitable for a wide range of drug delivery systems, including microspheres, nanoparticles, films, and gels.

5. Regulatory acceptance

Several natural polymers have been recognized as safe for pharmaceutical use and carry the Generally Recognized As Safe (GRAS) status from regulatory authorities like the FDA. This recognition simplifies the approval process for new formulations because the polymer excipients are already established as non-toxic, biocompatible, and safe for human use. Examples include starch, cellulose derivatives, gelatin, and alginate. Regulatory acceptance not only reduces developmental timelines but also enhances the likelihood of market approval.

CHALLENGES IN USING NATURAL POLYMERS

While natural polymers offer numerous advantages in sustained release drug delivery, their

use is not without challenges. Formulators often face several technical and practical hurdles when designing tablets or other dosage forms using these materials. The major challenges include:

1. Batch-to-Batch Variability

Natural polymers, being biologically derived, are subject to inherent variability. Factors such as plant source, harvest conditions, and extraction methods can lead to differences in viscosity, molecular weight, degree of polymerization, and swelling behavior. This variability can significantly affect the reproducibility of drug release profiles, making it difficult to guarantee consistent therapeutic outcomes. For instance, two batches of gum acacia or alginate may exhibit different gel strengths, which can alter the drug diffusion rate from a matrix tablet. Therefore, rigorous standardization and quality control are required to minimize batch-to-batch inconsistencies.

2. Moisture Sensitivity

Many natural polymers are hydrophilic and hygroscopic, meaning they readily absorb moisture from the environment. This property can lead to several stability issues during storage. Increased moisture content can accelerate hydrolysis or microbial growth, reduce tablet hardness, and alter the release profile of the drug. For example, starch and cellulose derivatives can swell excessively upon moisture uptake, causing premature drug release or deformation of the tablet. Effective packaging and moisture barrier strategies are often necessary to mitigate these issues.

3. Limited Mechanical Strength

Certain natural polymers produce dosage forms with poor mechanical properties, such as low hardness and high friability. Tablets formulated solely with some gums or polysaccharides may crumble easily during handling, transport, or packaging. To overcome this limitation, formulators often need to combine natural polymers with synthetic excipients or employ tableting aids to improve compressibility, cohesion, and mechanical stability. For example, blending chitosan with microcrystalline cellulose can enhance the tablet’s strength while retaining controlled release properties.

4. Compatibility Issues

Natural polymers may interact with the active pharmaceutical ingredient (API) or other

excipients in the formulation, potentially affecting drug stability or release kinetics. Some polymers can form hydrogen bonds or ionic interactions with drugs, which may alter solubility or cause chemical degradation. For instance, certain proteins or polysaccharides may catalyze hydrolysis of labile drugs or change their release behavior in acidic or basic environments. Careful pre-formulation studies, including compatibility testing and stress testing, are essential to ensure the stability and efficacy of the final product.

5. Scale-Up Challenges

Translating a formulation from laboratory to industrial scale can be more complicated with natural polymers than with synthetic ones. The inherent variability and sensitivity to environmental conditions make it difficult to achieve uniform mixing, consistent compression, and reproducible drug release profiles during large-scale production. Additionally, factors such as shear forces, moisture content, and heat during manufacturing can impact polymer properties. This necessitates meticulous process optimization, quality control, and monitoring during scale-up to maintain product performance.

SCOPE OF SUSTAINED RELEASE TABLETS USING NATURAL POLYMERS

The use of natural polymers in sustained release tablet formulations is gaining increasing attention in modern pharmaceutics. Their biocompatibility, biodegradability, and versatility align well with current trends towards eco-friendly and patient-centric drug delivery systems. The scope of their application is broad, particularly in chronic disease management, specialized populations, targeted therapy, and advanced formulation techniques. The key areas include:

1. Chronic Disease Management

Sustained release tablets using natural polymers are highly beneficial for patients with chronic conditions such as hypertension, diabetes, cardiovascular disorders, or arthritis. These conditions often require long-term medication with frequent dosing, which can lead to poor patient compliance. By incorporating natural polymers such as alginate, guar gum, or chitosan into the tablet matrix, drugs can be released gradually over an extended period. This reduces dosing frequency, maintains steady plasma drug levels, and improves adherence, ultimately enhancing therapeutic outcomes and patient quality of life.

2. Pediatric and Geriatric Formulations

Sensitive populations like children and the elderly require formulations that are safe, biocompatible, and gentle on the body. Natural polymers are generally well-tolerated and less likely to cause irritation or allergic reactions compared to synthetic excipients. For instance, formulations using gelatin, xanthan gum, or pectin can be designed as easy-to-swallow tablets with controlled release properties. This allows safer dosing and minimizes the risk of side effects, making them particularly suitable for pediatric and geriatric drug delivery.

3. Targeted Delivery

Natural polymers can be chemically or physically modified to achieve site-specific or pH-responsive drug release. For example, polymer matrices can be engineered to remain intact in the acidic environment of the stomach but swell and release the drug in the more neutral pH of the intestine. This property is highly advantageous for drugs that require absorption in specific regions of the gastrointestinal tract or for protecting drugs from degradation in the stomach. Polymers such as chitosan, alginate, and pectin are commonly used to design such targeted delivery systems.

4. Combination Therapy

Natural polymer matrices offer the flexibility to incorporate multiple drugs within a single dosage form, allowing synergistic or sequential release. This approach is useful in complex therapies, such as combination antihypertensive or anti-diabetic treatments, where controlling the release profile of each drug can optimize efficacy and reduce side effects. The ability to co-deliver drugs in a sustained manner reduces pill burden for patients and enhances therapeutic compliance, particularly in chronic disease management.

5. Integration with Modern Technologies

The versatility of natural polymers enables their integration with cutting-edge drug delivery technologies. For example, natural polymers can be combined with 3D printing to create patient-specific dosage forms with customized release profiles. Similarly, microencapsulation and nanotechnology approaches allow natural polymers to form nanoparticles or microspheres that improve solubility, protect labile drugs, and achieve controlled release. These advancements open avenues for personalized medicine, smart drug delivery systems, and improved pharmacokinetic control.

FORMULATION STRATEGIES

The formulation of sustained release tablets using natural polymers typically involves the following steps:

1. **Selection of polymer** – the choice depends on drug solubility, desired release rate, and mechanism of release (diffusion, erosion, or swelling-controlled). For example, highly water-soluble drugs may require high-viscosity polymers to retard release, whereas poorly soluble drugs may need polymers that promote gradual erosion.
2. **Drug-polymer ratio optimization** – varying the proportion of polymer to drug influences the release kinetics. Increasing polymer content generally slows down drug release by forming a denser matrix.
3. **Tablet preparation methods** – several methods can be employed, including wet granulation, dry granulation, direct compression, and extrusion-spheronization. Wet granulation is commonly used to ensure uniform drug distribution and proper matrix formation.
4. **Use of additives** – plasticizers, lubricants, and fillers may be added to improve mechanical strength, compressibility, and flow properties of the tablets.
5. **Evaluation of release kinetics** – drug release can be modulated by adjusting polymer type, particle size, and tablet geometry. The release kinetics are usually fitted to mathematical models such as zero-order, first-order, Higuchi, or Korsmeyer-Peppas models to understand mechanism.

EVALUATION OF SUSTAINED RELEASE TABLETS

Proper evaluation of SR tablets is essential to ensure their efficacy, stability, and reproducibility. The key evaluation parameters include:

1. **Physical characterization** –
   - **Appearance and color** – uniformity indicates proper blending of polymer and drug.
   - **Hardness and friability** – ensure tablets withstand handling and transportation.
   - **Weight variation** – uniform weight distribution indicates consistent dosing.
2. **Drug content uniformity** – determines whether each tablet contains the intended drug dose within permissible limits.
3. **Swelling and erosion studies** – natural polymers often control release through swelling. The degree of swelling is measured by immersing tablets in dissolution media and

calculating percent weight gain. Erosion studies indicate polymer matrix degradation over time.

4. **In vitro dissolution studies** – performed using USP type II (paddle) or type I (basket) apparatus. Dissolution profiles help determine drug release rate and mechanism.
5. **Kinetic modeling of drug release** – release data are analyzed using zero-order, first-order, Higuchi, and Korsmeyer-Peppas equations. This provides insight into whether the release is diffusion-controlled, erosion-controlled, or anomalous.
6. **Stability studies** – tablets are stored under accelerated conditions (40°C ± 2°C, 75% RH ± 5%) to evaluate changes in physical appearance, hardness, and drug release over time.

Table 2: Evaluation Parameters of Sustained Release Tablets

Parameter	Purpose	Method/Instrument	Acceptance Criteria
Hardness	Mechanical strength	Monsanto Hardness Tester	4–6 kg/cm²
Friability	Resistance to abrasion	Roche Friabilator	<1% weight loss
Weight variation	Dose uniformity	Analytical balance	±5%
Drug content	Uniformity of drug distribution	UV-Vis or HPLC	95–105% of labeled amount
Swelling index	Matrix swelling capacity	Immersion in dissolution medium	50–200% increase
In vitro dissolution	Drug release profile	USP Type I/II apparatus	≥80% drug release over desired time

MECHANISM OF DRUG RELEASE

Natural polymer-based SR tablets typically follow one or more of the following release mechanisms:

1. **Diffusion-controlled release** – drug diffuses through a swollen polymer matrix.
2. **Erosion-controlled release** – polymer matrix gradually erodes, releasing drug.
3. **Swelling-controlled release** – polymer swells upon hydration, creating a gel barrier that controls drug diffusion.
4. **Combination mechanism** – in many cases, release is governed by a combination of diffusion, swelling, and erosion, leading to complex but predictable release profiles.

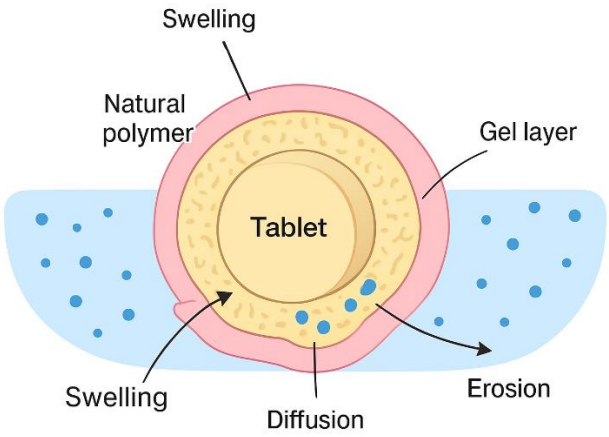

Figure 1: Schematic of Drug Release Mechanism from Natural Polymer Matrix

FUTURE PERSPECTIVES

The field of sustained release using natural polymers continues to evolve. Some emerging trends include:

1. **Polymer modification** – chemical modification or cross-linking can fine-tune drug release rates.
2. **Nanotechnology integration** – incorporating drugs into polymeric nanoparticles embedded in matrix tablets enhances bioavailability and controls release.
3. **3D printing** – allows precise control of tablet geometry, porosity, and drug-polymer distribution for personalized therapy.
4. **Combination with synthetic polymers** – hybrid matrices can overcome limitations such as poor mechanical strength or high variability of natural polymers.

CLINICAL RELEVANCE

Sustained release tablets formulated using natural polymers provide clinical benefits by maintaining therapeutic plasma drug concentrations, reducing side effects associated with peak concentrations, and improving adherence to long-term therapy. For example, SR tablets of antihypertensive or antidiabetic drugs reduce the need for multiple daily dosing, improving patient quality of life.

CONCLUSION

The study successfully demonstrates the feasibility of using natural polymers as effective release-controlling agents in sustained release formulations. The resulting tablets maintained

their physical and chemical integrity while providing predictable release kinetics. The advantages of eco-friendly, cost-effective, and safe polymers make them ideal for industrial applications. Future investigations should explore the synergistic use of multiple natural polymers to tailor specific release characteristics. This work supports the growing shift toward sustainable pharmaceutical practices without compromising therapeutic efficiency.

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