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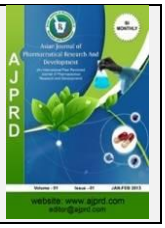

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Research Article

Functional and Mechanistic Insights into Natural Pharmaceutical Excipients

Dehuti Fate, Prasad Deshmukh*, Tejas Dhok, Kundan Sawale, Pallavi Sawwalakhe, Dipti Ruikar

Dept. of Pharmaceutics, P. R. Pote Patil College of Pharmacy Amravati, Maharashtra. India.

A B S T R A C T

Natural excipients derived from from natural sources have emerged as promising alternatives to synthetic polymers in pharmaceutical formulations. These excipients offer advantages such as biocompatibility, biodegradability, low toxicity and cost-effectiveness. The present review provides a comprehensive analysis of selected natural polymers, including gaur gum, neem gum, gum ghatti, khaya gum, tamarind seed gum and agar, with emphasis on their physicochemical properties, extraction methods and pharmaceutical applications. Particular focus is given to their role in controlled and sustained drug delivery systems. A comparative evaluation highlights the influence of swelling behavior, viscosity and gel-forming ability on drug release kinetics. Despite their advantages, limitations such as batch variability and microbial contamination restrict their large-scale application. Recent advancements including polymer modification and co-processing techniques, have been discussed. Overall, natural excipients present a promising alternative to synthetic polymers, with significant potential in the development of novel and sustainable drug delivery systems.

Keywords: Natural polymers, Gaur gum, Neem gum, Gum Ghatti

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*Address for Correspondence:

Dr. Prasad R. Deshmukh, HOD of Pharmaceutics, P. R. Pote Patil College of Pharmacy, Amravati, 444604, Maharashtra. India

INTRODUCTION

Pharmaceutical excipients play a crucial role in the formulation of drug products, serving as inert substances that facilitate the delivery of active pharmaceutical ingredients (APIs) to the body. Defined as inactive ingredients, excipients are integral in enhancing the stability, bioavailability, and overall efficacy of pharmaceutical formulations. They are classified based on their origin into three main categories: natural, semisynthetic, and synthetic excipients.

The choice of excipients significantly influences the physicochemical properties of pharmaceutical formulations, including their flowability, compressibility, and dissolution rates. For instance, disintegrants like croscarmellose sodium facilitate the breakup of tablets in the gastrointestinal tract, enhancing drug absorption. Binders, such as starch and gelatin, help in tablet formation, ensuring mechanical strength and integrity.

Moreover, excipients can also serve specific functions, such as stabilizing active ingredients against degradation or controlling the release rate of drugs from dosage forms. Recent advancements in excipient technology have led to the development of multifunctional excipients that can perform several roles within a single formulation, enhancing efficiency and efficacy.

Excipients are crucial for stabilizing and delivering active pharmaceutical ingredients effectively. They enhance drug bioavailability, ensure proper dosage form structure, and improve patient compliance. By controlling drug release and protecting APIs from degradation, they ensure therapeutic efficacy. Careful selection of excipients ensures safety, stability, and overall product quality in formulations.

In conclusion, pharmaceutical excipients are indispensable components of drug formulations, impacting the performance, safety, and efficacy of therapeutic products. Understanding the various types of excipients and their functions is essential for pharmaceutical scientists and

formulators aiming to develop effective and stable drug products (1).

Classification of Excipients

Excipients are broadly classified based on their origin into natural, semisynthetic, and synthetic excipients.

1. Natural Excipients

Natural excipients are derived from natural sources such as plants, animals, and minerals. They are biodegradable, biocompatible, economical, and widely used in pharmaceutical formulation (2).

Examples: Acacia gum, starch, alginates, pectin, gelatin.

2. Semisynthetic Excipients

Semisynthetic excipients are chemically modified derivatives of natural polymers that exhibit improved stability and functionality (3).

Examples: Hydroxypropyl methylcellulose (HPMC), carboxymethyl cellulose (CMC), ethylcellulose.

3. Synthetic Excipients

Synthetic excipients are chemically synthesized materials designed to provide specific pharmaceutical properties such as enhanced stability and controlled drug release (4).

Examples: Polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), carbomers, poloxamers.

Role of Natural Excipients in Pharmaceutical Formulations (5)

Natural excipients perform several important functions in pharmaceutical dosage forms.

- **Binders**

  Binders provide cohesiveness to powders during tablet manufacturing and improve tablet strength and integrity.

  Examples: Acacia gum, guar gum, starch

- **Diluents**

  Diluents increase the bulk of formulations when the dose of active ingredient is low.

  Examples: Starch, microcrystalline cellulose

- **Disintegrants**

  Disintegrants facilitate tablet breakup after administration, promoting rapid drug release and absorption.

  Examples: Starch, psyllium mucilage.

- **Coating and Stabilizing Agents**

  Natural polymers protect formulations from environmental conditions and can also control drug release.

  Examples: Pectin, cellulose derivatives.

- **Viscosity Enhancing Agents**

  Natural gums and mucilages are used to control the viscosity of liquid and semisolid formulations.

Examples: Xanthan gum, agar, guar gum.

Advantages of Natural Excipients

Natural excipients offer several advantages in pharmaceutical formulations:

- Biodegradable and environmentally friendly
- Biocompatible and non-toxic
- Economical and easily available
- Safe with minimal side effects
- Regulatory acceptance due to historical use
- Versatile pharmaceutical applications
- Suitable for controlled drug delivery systems (6)

Disadvantages of Natural Excipients

Despite their benefits, natural excipients possess certain limitations:

- Batch-to-batch variability
- Risk of microbial contamination
- Moisture sensitivity
- Limited functional consistency
- Stability issues during storage
- Complex purification processes (7)

Applications of Natural Excipients

Natural excipients are widely used in:

- Tablets and capsules
- Controlled release formulations
- Suspensions and emulsions
- Gels and semisolid preparations
- Mucoadhesive drug delivery systems
- Sustained and targeted drug delivery systems

Their swelling, gel-forming, and biodegradable properties make them suitable for advanced pharmaceutical applications (8).

Natural Excipients:

Natural excipients derived from plant secondary metabolites have gained significant importance in pharmaceutical formulations due to their biocompatibility, low toxicity, and eco-friendly nature. They are widely used in novel drug delivery systems as binders, diluents, disintegrants, gelling, thickening, and suspending agents. Extensive research has focused on their isolation, characterization, and application in formulation development, highlighting their potential as sustainable and effective alternatives to synthetic excipients in modern pharmaceutical industries.

1. Neem Gum:

Neem gum is a natural excipient obtained from Azadirachta indica belonging to the family Meliaceae. It is widely used in pharmaceutical formulations as a binder, stabilizer, thickening agent, and release-retarding polymer. Due to its natural origin, biocompatibility, and safety, neem gum has gained importance in novel drug delivery systems (9). It also exhibits gel-forming and film-forming properties, making it suitable for topical and controlled release formulations. Pharmacognostically, neem gum appears as a yellowish to brownish resinous substance with a characteristic odor and bitter taste (10). It is soluble in water and some organic solvents. Neem gum is isolated by collecting exudates from neem tree incisions, followed by drying, pulverization, and purification using distilled water, acetone, and ethanol precipitation methods. The purified gum is then dried and stored in airtight containers for pharmaceutical use.

Various researchers have extensively investigated the pharmaceutical applications of neem gum due to its natural origin, biocompatibility, and multifunctional properties. Several studies have reported its potential as a binder, thickening agent, stabilizer, and release-retarding polymer in different pharmaceutical formulations. The following literature reviews summarize the work carried out by various authors on the pharmaceutical importance and applications of neem gum.

The floating tablets were prepared by direct compression technique it may be concluded from the study that slow and sustained release of Esomeprazole over a period of 12 hr was obtained by the using Moringa gum, Azadirachta indica gum, Sodium alginate was successful in the formulation of floating tablet and at the same time itis effective in retarding the drug release.The drug release profiles showed that, neem gum tablets released 93% of the drug within 8 hours. In comparison Moringa gum tablets released 89% of the drugwithin 9 hoursand sodium alginate tablets released 89% over 9 hours (11).

Metronidazole granules were prepared by wet granulation technique with the extracted neem gum at varyingconcentrations of 25-50%w/w. Neem gum exhibited good mucoadhesive property with mucoadhesive strength from 0.63- 4.95 N. combination of neem gum HPMC gives synergistic mucoadhesive effect with strength of 4.95 N (12).

Ketoprofen has low biological half-life and poor water solubility hence require frequent administration. Ketoprofen matrix tablets were formulated by employing neem gum as a release rate retardant material and used in 10%, 20%, 30%, and 40% Concentration levels using wet granulation method. neem gum at 30% concentration level released 98.2% drug in 12 hours is selected as optimized formula, it is evident that this formulation has shown drug release by zero order kinetics (13).

Fexofenadine hydrochloride had very poor flow properties. So, the ODTs were prepared bywet granulation method using Neem gum (a naturally occurring plant gum) as binder or granulating agent. And this new natural plant gum was compared with the other granulating agents like starch, acacia, xanthan gum and povidone k30 for its granulating property and drug release profile for making ODTs. The results states that the Neem gum in 3%w/v was better over the other granulating agents (starch, acacia, xanthan gum and povidone k30) for the preparation of ODT.

From the reported literature, it can be concluded that neem gum possesses significant pharmaceutical potential due to its excellent binding, swelling, thickening, and controlled release properties. Its natural origin, biocompatibility, and multifunctional applications make it a promising excipient for the development of novel drug delivery systems (15).

2. Guar Gum:

Guar gum is a natural excipient obtained from Cyamopsis tetragonoloba belonging to the family Fabaceae. It is widely used in pharmaceutical formulations due to its thickening, stabilizing, mucoadhesive, and sustained release properties. Guar gum appears as a free-flowing white to off-white powder, which is odorless, tasteless, and soluble in cold water, forming a viscous solution (16). It is mainly cultivated in India and Pakistan. Guar gum is isolated from guar seeds through cleaning, dehusking, grinding, extraction with water, filtration, alcohol precipitation, washing, and drying processes. Due to its ability to modify drug release and enhance formulation stability, guar gum is extensively used in controlled and sustained drug delivery systems.

Various researchers have extensively explored the pharmaceutical applications of guar gum due to its excellent thickening, stabilizing, mucoadhesive, and controlled release properties. Several studies have demonstrated its potential as a natural excipient in sustained release, matrix, and novel drug delivery systems.

Study demonstrated that a successful colon-specific system using KTM-GG compression coated tablets for drugr elease in the stomach and small intestine. In vitro drug release studies showed that the 28.5%conc. level of guar gum formulation released a significant amount of drug in the colon with minimal release in a 5h lag period. The pharmacokinetic parameters showed negligible drug release in the stomach and small intestine but significant release in the colon, making GG compression coated tablets a promising approach for KTM colon targeting (17).

Guar gum microspheres were prepared using glutaraldehyde as across-linking agent, with varying concentrations greatly affecting their characteristics. Aceclofenac loaded microspheres showed a high entrapment efficiency of 79.99%. In vitrorelease was investigatedin gastro intestinal mediums with and without rat ceacal contents, with a significant increase in drug release (83.23%) in mediums with 4% rat ceacal content. In vivo anti-inflammatory activity confirmed the optimized formulation's potential for targeting the colon for treating rheumatoid arthritis. Guar gum microspheres showed adequate potential in targeting the colon and maximizing drug release upon enzymatic action (18).

Slow and controlled release of zidovudineovera period of 12 hours was obtained from matrix tablets (15% -35%).

Use of natural hydrophilic polymer like guar gum was successful in the formation of matrix and at the sametime it is effective in re tarding the drug release. Among all the formulation, 15% conc, level shows that 95.97% of drug release at the end of 12 hours. The cumulative percentage drug was decreased by increase in polymer concentration (19).

The in vivo evaluation of guar gum-based colon-targeted mebendazole tablets in human volunteers showed delayed Tmax, prolonged absorption time, decreased Cmax, and decreased absorption rate constant. This suggests that the drug was not released significantly in the stomach and smallintestine but was delivered to the human colon, resulting in slow absorption and local action. Further in vivo evaluation would provide more realistic data on the usefulness of guar gum as a carrier for colonic delivery in helminthiasis treatment (20).

Guar gum, when compressed into tablets, can prevent drug release in the stomach and small intestine, as demonstrated in invitro drug release studies. This is achieved under conditions mimicking mouth-to-colon transit. Guar gum's ability to release the drug in the colon is demonstrated through in vitro testing with ratcaecal contents (4% w/v level in the dissolution medium after 7 days of enzyme induction provide the best conditions for assessing the susceptibility of guar gum to colonic bacterial degradation), which provide optimal conditions for assessing the delivery carrier (21).

3. Gum Ghatti:

Gum Ghatti is a natural exudate obtained from Anogeissus latifolia belonging to the family Combretaceae. It is widely used in pharmaceutical formulations due to its emulsifying, thickening, binding, and film-forming properties. Gum Ghatti is composed mainly of galactose, arabinose, mannose, and glucuronic acid. It appears as an off-white to light brown powder or granules with a faint odor and bland taste. The gum swells in water to form a viscous colloidal solution (22). It is commonly found in the dry deciduous forests of India. Gum Ghatti is isolated by collecting gum exudates from tree bark, followed by cleaning, dissolution in water, filtration, alcohol precipitation, drying, and powdering. Due to its excellent stabilizing and controlled release properties, Gum Ghatti is widely utilized in tablets, suspensions, emulsions, and coating formulations (23).

Various researchers have investigated the pharmaceutical applications of Gum Ghatti due to its excellent emulsifying, binding, thickening, and film-forming properties. Several studies have reported its potential as a natural excipient in tablet formulations, suspensions, emulsions, and controlled drug delivery systems.

The polymer-drug tablets were prepared by wet granulation technique. From the present study, it can be concluded that ghatti gum, which are natural andbiodegradablepolymers can be employed foruse as carriers in developing colon targeted drug deliverysystems. However,ghatti gum acta as a carrier for colon targeting (24).

The study found that Atorvastatin calcium can be prepared using solvent evaporation method, which is more effective than solid dispersion techniques. The study found that the gum ghatti, a natural polymer, ismore effective than soluplus. This improves the solubility and dissolution rate of solid dispersion for oral dosage forms of immediate release tablets (25).

The study developed a sustained-release gum ghatti mucoadhesive oral matrix tablet using direct compression without time-consuming granulation processes. The tablet aims to provide effective therapy with enhanced bioavailability and better drug targeting.The combination of gum ghatti polymers and HPMCK15M is more effective for desired gastric retention and better drug release profile (26).

This study suggests that curcumin, a treatment for colon cancer, can be effectively delivered to the colon using guar gum or gum ghatti, which are natural polymers with a highly branched molecular structure that resists enzymatic breakdown in the digestive tract, thereby increasing bioavailability and improving the treatment efficacy of colon cancer treatment (27).

4. Khaya Gum:

Khaya gum is a natural exudate obtained from Khaya senegalensis belonging to the family Meliaceae. It is widely used in pharmaceutical formulations as a binder, stabilizer, emulsifier, suspending agent, and thickening agent. Khaya gum forms a viscous gel-like solution in water and improves tablet cohesion, mechanical strength, and disintegration properties. It appears as a translucent amber to light brown solid or granule with a mild woody odor and bland taste (28). The gum is mainly found in tropical African regions and savannas. Khaya gum is isolated by collecting gum exudates from bark incisions, followed by cleaning, dissolution in warm water, filtration, precipitation using ethanol or acetone, washing, drying, and powdering. Due to its biodegradability, non-toxicity, and compatibility with pharmaceutical ingredients, Khaya gum serves as an effective natural alternative to synthetic excipients in pharmaceutical formulations.

Various researchers have explored the pharmaceutical applications of Khaya gum due to its excellent binding, thickening, emulsifying, and stabilizing properties. Several studies have demonstrated its potential as a natural excipient in tablet formulations, suspensions, and controlled drug delivery systems

The study suggests that flocculated suspensions are crucial for long-term stability, and the concentration of gum used as a wetting and suspending agent must be determined. Khaya senegalensis gum, at 0.2%w/v, successfully suspended cotrimoxazole, maintaining its flocculation and aesthetic appearance throughout storage. The gradual release rate of khaya gum suspension may offer potential for sustained release suspensions, indicating its potential in this field (29).

Previous studies haveindicated that locust bean gum alone is not effective in controlling drug release. However, this studyshows that combining locust bean gum with khaya gum has a synergistic effect in controlling the release of

diltiazem. Furthermore, combining khaya gum with HPMC results in even greater sustained release compared to khaya gum alone or its combination with locust bean gum.The formulation containing khaya and locust bean gums in a 1:2 ratio was found to be closest to the commercial diltiazem tablet used as a standard (30).

Khayagum, abindingagent from Khay agrandifolia, significantly influenced the bulk, compressional, and tableting characteristics of a paracetamol tablet formulation, out per forming standard binders PVP and gelatin. Formulations containing khaya gum exhibited more densification than formulations containing PVP and gelatin during die filling, but less densification due to rearrangement at low pressures (31).

5. Tamarind Seed:

Tamarind seed gum is a natural polysaccharide obtained from Tamarindus indica belonging to the family Fabaceae. It mainly consists of xyloglucan and is widely used in pharmaceutical formulations as a thickening, stabilizing, gelling, and bioadhesive agent. Tamarind seed gum forms a highly viscous solution in water and is extensively utilized in controlled drug delivery systems and tablet formulations. It appears as a white to light yellowish-brown powder with a mild odor and bland taste (32). The gum is partially soluble in cold water and forms a viscous solution in hot water (33). Tamarind seed gum is isolated by seed collection, soaking, dehulling, hot water extraction, filtration, alcohol precipitation, washing, drying, and grinding processes. Due to its biodegradability, biocompatibility, and ability to enhance drug release and stability, tamarind seed gum has gained significant importance as a natural pharmaceutical excipient (34).

Various researchers have extensively investigated the pharmaceutical applications of tamarind seed gum due to its excellent thickening, gelling, bioadhesive, and controlled release properties. Several studies have highlighted its potential as a natural excipient in tablet formulations and novel drug delivery systems.

The present investigation study revealed that the great super disintegration potential of modified Tamarind seed gum. The FDT's tablet prepared from calcium complexed Tamarind seed gum (7.5%) showed faster disintegration of tablet as compared to the synthetic superdisintegrant (Sodium starch glycolate). The carboxymethylation of the Tamarind seed gum is used to increase the hydrophilicity to the gum, so that it can easily disintegrate in the gastric fluid (35).

Modified gum, a promising biopolymer, was modified by carboxymethylation, enhancing water solubility and flowability properties. It also served as a dry binder in tablet formulation, increasing hardness and decreasing friability. The study suggests that modified gum by carboxymethylation could have further pharmaceutical dry binder applications in tablet formulation (36).

Thecolonisacrucialsitefordrugabsorptionanddelivery,withl ow surface area compared to the small intestine. Tamarind seed polysaccharide, prepared as matrix tablets, protects drugs from being released in the upper gastro intestinal tract. In vitro biodegradability studies show TSP can release drugs in pH 6.8 Sorenson's phosphate buffer with RCC, The RCC 4% w/v level after 7 days of enzyme induction degraded tamarind seed polysaccharide remarkably and its presence in dissolution medium provided best conditions for assessing the susceptibility of tamarind seed polysaccharide to colonic bacterial degradation (37).

6. Agar

Agar is a natural polysaccharide obtained from red algae such as Gelidium and Gracilaria. It is widely used in pharmaceutical formulations due to its excellent gelling, thickening, stabilizing, and binding properties. Agar is commonly employed in gels, suspensions, tablet formulations, and controlled drug delivery systems. It appears as translucent strips or powder, is odorless and tasteless, and forms a gel when dissolved in hot water. Agar is isolated by harvesting and washing red algae, followed by boiling, filtration, cooling, freezing-thawing, drying, and powdering processes. Due to its non-toxic, biocompatible, and versatile nature, agar (39).

Various researchers have extensively investigated the pharmaceutical applications of agar due to its excellent thickening, gelling, bioadhesive, and controlled release properties. Several studies have highlighted its potential as a natural excipient in tablet formulations and novel drug delivery systems.

Soft chewable tablets were prepared formainly pediatric and geriatric patient.This tablets are manufactured by melt granulation method. The tablets had an immediate-release profile in the fragmented form,with100% of the drug released within 30 min of the dissolution process. Meanwhile, in the intact form, it displayed an extended-release profile. These findings pave the way for the pharmaceutical industry to use the melt granulation method to produce chewable tablets (40).

Fast dissolving tablet of Tenoxicam can be prepared by direct compression method and Croscarmellose sodium,Treated agar; cross povidone as Superdisintegrants was found to be the best than other Superdisintegrants. Formulation showed the least and the highest release of more than 93.33% of the drug in just 40 seconds. Formulation has water absorption ratio and faster swelling ability of the disintegration in presence of little amount of water (41).

Flurbiprofen FDT's were successfully prepared using natural superdisintegrants modified agar through direct compression method. The tablets demonstrated excellent hardness, friability, compression, disintegration, and dissolutionproperties, disintegrating rapidly with in the specified time limit. Moreover, they exhibited complete drug release within a short period, which is beneficial for in vivo bioavailability.The isolated natural superdisintegrants showed promis ingresults, serving as effective alternatives to synthetic disintegrants. Importantly, the formulations remained stable throughout the stability period (42).

Pediatrics and geriatric categories with difficulties in swallowing hence orodispersible (ORD) tablets were

prepared using natural super disintegrants Agar. Tablets are prepared by using wet granulation method.5% concentration has better release profile over another formulation. It was evident that rate of drug release can be optimized using natural disintegrants for orodispersible formulations (43).

CONCLUSION:

This study high lights the use of natural excipients in pharmaceutical formulations, and their multi functionality, biocompatibility, and cost-effectivenes sby serving as binders, disintegrants, stabilizers, thickeners, and more. Natural excipientslike neem gum, guar gum, gumghatti, khayagum, tamarind seed gum, and agar demonstrate their versatility inenhancing drug delivery. Each excipients contributes uniquely to formulation designs, suchas Neem gum's gel-form ingability for controlled release, Guargum'sapplication insustained-release systems, Gum Ghattiin colon targeting drug delivery, Khaya gum in flocculation of suspension, Tamarind gum and Agar as superdisintegrating agents.

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