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Evaluation of Probiotic-Loaded Pharmaceutical Formulations for Prevention and Treatment of Gastrointestinal Infections

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ABSTRACT

Gastrointestinal (GI) infections are a continuing worldwide public health problem and are responsible for creating a significant portion of the illnesses and deaths attributed to children, elderly, and immunocompromised individuals. The increasing rates of antibiotic resistance and changing intestinal flora after taking antibiotics have led to a renewed interest in using probiotics as an alternative or additional method of treating infections. Probiotics are defined as live microorganisms that confer health benefits when consumed in sufficient quantities by restoring the healthy balance of microorganisms in the intestine, enhancing the integrity of the intestinal barrier function, preventing the growth of harmful microorganisms in the intestines, and regulating immune responses. The effectiveness of probiotics as therapeutic agents is also dependent upon their ability to survive the manufacturing and storage process and also survive the harsh environment of the GI tract. Various pharmaceutical formulations have been created to improve the physical stability and viability of probiotics (e.g., capsules, tablets, sachets, microencapsulation and nanoencapsulation, hydrogels, and lipid-based delivery systems) and facilitate a targeted release of the probiotics in the intestine. This review provides an overview of the latest developments in the area of probiotic delivery systems as they are being used to help manage GI infections, including commonly used probiotic strains, formulation technologies, evaluation methods, and the clinical applications of probiotics in the prevention and treatment of GI infections caused by Helicobacter pylori, Clostridioides difficile, pathogenic Escherichia coli, Salmonella, and rotavirus. In addition, we will discuss current challenges to probiotic viability, formulation stability, regulatory considerations and quality control before discussing emerging technologies such as nanotechnology, synbiotics, precision probiotics, and microbiome-based therapies that will help improve the development of new probiotic delivery systems to improve GI health and minimize the burden of infectious diseases.

Keywords: Probiotics; Gastrointestinal infections; Pharmaceutical formulations; Microencapsulation; Drug delivery; Gut microbiota; Synbiotics; Microbiome.

1. Introduction

One of the leading causes of morbidity and mortality around the world are Gastrointestinal (GI) infections, impacting millions of people each year. GI infections can develop due to infection by a virus, bacteria, fungus, or parasite (Examples: Helicobacter pylori,

Clostridioides difficile, pathogenic R. coli, Salmonella enterica, Shigella spp., Campylobacter jejuni, etc). Clinical manifestations of GI infections can range from mild diarrhea and abdominal pain to dehydration, inflammatory bowel disease, sepsis, and potentially life-threatening complications, particularly in children, the elderly, and immunocompromised patients [1].

Most bacterial GI infections are treated with antibiotics, however, due to misuse or overuse of antibiotics, there is a rapid rise in antimicrobial resistance (AMR). In addition, antibiotics can disrupt the normal gut microbiota leading to dysbiosis and decreased colonization resistance resulting in a higher likelihood of recurrent infections (e.g., Clostridioides difficile-associated diarrhea). Therefore, there is an increase in demand for alternative therapies that restore microbial homeostasis with little to no use of antibiotics.

Probiotics are live microorganisms that are provided to the host in sufficient quantities through diet or supplements and provide health benefits. The most frequently used strains of probiotics are species of Lactobacillus, Bifidobacterium, and Saccharomyces. Probiotic bacteria promote GI health by providing a variety of benefits, including competition with pathogenic microorganisms for colonization sites, producing antimicrobial metabolites (e.g., bacteriocins and organic acids), supporting the integrity of the epithelial barrier, modulating the mucosal immune response, and restoring normal diversity of gut microbiota.

Despite their potentially beneficial therapeutic effects, ensuring the viability of probiotics throughout the manufacturing process, storage of the product, and transport through the GI tract is a significant challenge. Probiotics can be adversely affected by a variety of factors, including moisture, oxygen, elevated temperatures, gastric acidity, digestive enzymes, and bile salts prior to intestinal delivery. Therefore, extensive research has been directed toward the development of newer pharmaceutical formulations capable of protecting probiotic organisms from these aforementioned factors while allowing for controlled release of probiotics at the desired site of action [2].

Several types of delivery systems that have demonstrated greater stability, shelf life, and colonization of probiotics within the intestines include hard gelatin capsules, tablets, powders, sachets, oral suspensions, microencapsulated products, nanoencapsulated products, hydrogels, lipid-based carriers, and gastro-resistant polymer coated dosage forms. The emergence of these newer products and delivery systems has expanded the use of probiotics to prevent and treat GI infections, and improve patient compliance and treatment outcomes [3-5].

The objective of this review is to provide a comprehensive overview of probiotic-loaded pharmaceutical dosage forms, including their mechanisms of action, development and formulation technologies, evaluation methods, clinical uses, current limitations, and both current and future opportunities to prevent and treat GI infections.

2. Probiotics and Gastrointestinal Health

The gut microbiota, which consists of millions of microbes living in the human gastrointestinal (GI) tract, performs many important functions that are essential to humans, including aiding in digestion and nutrient metabolism, regulating the immune system, and providing a barrier that protects against pathogenic microbes. Maintaining a balanced gut microbiota through harmonious relationships between humans and their gut microbiota is essential to maintaining gastrointestinal (GI) health; on the other hand, disruptions to the gut microbiota balance (dysbiosis) can lead to gastrointestinal infections, inflammatory bowel disease (IBD), antibiotic-associated diarrhea (AAD), irritable bowel syndrome (IBS) and many other metabolic disorders [6].

Probiotics are beneficial microbes that aid in restoring the balance of the gut microbiota by improving gut health. The primary genera of probiotics used in clinical studies include Lactobacillus, Bifidobacterium, Saccharomyces, Bacillus and Lacticaseibacillus. All of these microorganisms exhibit substantial therapeutic potential due to their ability to prevent or treat gastrointestinal infections.

Probiotics exert their beneficial effects in many different ways. One mechanism is by competing with pathogenic microbes for nutrients and for binding sites on the intestinal epithelium, which prevents pathogens from colonizing the intestines. Additionally, probiotics produce antimicrobial substances, including lactic acid, acetic acid, hydrogen peroxide and bacteriocins, which inhibit the growth of pathogenic bacteria. Probiotics also enhance the integrity of the intestinal epithelial tight junctions, increase the production of mucus, and improve the integrity of the intestinal barrier, thus decreasing the translocation of bacteria across the intestinal mucosa [7].

A second mechanism by which probiotics exert their beneficial effects is through modulating the host immune response. Probiotics stimulate the production of secretory IgA, regulate the secretion of cytokines, enhance the activity of macrophages and dendritic cells, and promote anti-inflammatory responses. The immunomodulatory effects of probiotics play a critical role in enhancing the ability to resist GI pathogens and in reducing intestinal inflammation [8].

Clinical data from randomized controlled trials demonstrate that probiotics effectively reduce the incidence and severity of many types of gastrointestinal infections, including AAD, Clostridioides difficile infections, Helicobacter pylori, infectious diarrhea, and rotavirus-associated gastroenteritis. Probiotics may also help decrease the duration of acute diarrhea and aid recovery following antibiotics by replenishing the normal gut microbiota.

Table 1. Common Probiotic Microorganisms Used in Gastrointestinal Disorders

biotic Strain	**jor Therapeutic Applications**
tobacillus rhamnosus G	ibiotic-associated diarrhea, acute infectious diarrhea

ctobacillus acidophilus	t microbiota restoration, gastrointestinal infections
idobacterium bifidum	mune modulation, inflammatory bowel disorders
idobacterium longum	estinal barrier protection, diarrhea prevention
charomyces boulardii	*ostridioides difficile* infection, traveler's diarrhea
cillus coagulans	gestive health, inflammatory bowel conditions
ticaseibacillus casei	vention of gastrointestinal infections, immune enhanceme

3. Probiotic-Loaded Pharmaceutical Formulations

The ability of probiotics to have therapeutic effects is greatly influenced by the prompt delivery of live microorganisms from manufacturing, through storage, to passage through the gastrointestinal tract. There have been various pharmaceutical development efforts made to protect probiotic microorganisms from environmental stressors and ensure their targeted delivery into the intestines [9].

3.1 Conventional Dosage Forms of Probiotics

The most common conventional probiotic dosage formulations are capsules, tablets, powders, granules, sachets, and oral solutions. Capsules are the most frequently used dosage form as they offer maximum protection against moisture and oxygen exposure and yield better patient compliance than other formulations. The use of enteric-coated capsules to deliver probiotics add an additional layer of protection against gastric acid allowing viable microorganisms to be released directly into the intestine [10].

3.2 Microencapsulated Probiotics

Microencapsulation is regarded as one of the best methods of improving probiotic product stability. Microencapsulation is a method of enclosing probiotics in protective polymeric substances such as alginate, chitosan, pectin, carrageenan, gelatin, or derivatives of cellulose. The polymer coating provided by microencapsulation acts as a protective barrier for probiotics enabling them to survive through acidity from gastric juices, bile salts, exposure to oxygen, and heat while extending the shelf life and enhancing the delivery of probiotics to the intestines [11].

3.3 Nanoencapsulated Probiotics

Nanoencapsulation uses particles that are smaller than 100 nanometers to enhance the protection and controlled release capabilities of probiotic microorganisms. Polymeric nanoparticles, lipid nanoparticles, nanofibers, and nanogels enhance the stability of probiotics, improve mucoadhesion, and allow for site-specific delivery of probiotic microorganisms to the small intestine. Nanoencapsulation has also been shown to increase the survival of probiotics through the gastrointestinal system [12].

3.4 Lipid-Based Probiotic Delivery Systems

Solid lipid nanoparticles (SLN), nanostructured lipid carriers (NLC), liposomes, and nanoemulsions have been developed as lipid-based probiotic carrier systems. All these systems provide sustained release of probiotics, protection from degradation by gastric acid, and improved colonization of the intestinal mucosa [13].

3.5 Hydrogel and Smart Delivery Systems

Hydrogel formulations can be made from substances such as alginate, chitosan, hyaluronic acid, and derivatives of cellulose, which allows for the hydration of probiotics. Hydrogel formulations allow for the controlled release of probiotics as well as an excellent ability to retain moisture. Stimulus responsive hydrogels that are designed to respond to either pH or enzymatic response when they are located within the GI tract represent a new approach to deliver probiotics to specific locations within the GI tract [14].

Table 2. Pharmaceutical Formulations for Probiotic Delivery

Formulation	Advantages	Limitations
Capsules	Easy administration, improved stability	Limited protection without ente coating
Tablets	Good patient compliance	Compression may reduce cell viability
Sachets/Powders	Convenient and economical	Moisture sensitivity
Microcapsules	Excellent protection, prolonged viability	Complex manufacturing
Nanoencapsulation	Targeted delivery, controlled release	Higher production cost
Liposomes	Enhanced stability and bioavailability	Limited long-term stability
Hydrogels	Sustained release, pH-responsive delivery	Scale-up challenges
Nanostructured Lipid Carriers	High encapsulation efficiency	Formulation optimization required

4. Evaluation of Probiotic-Loaded Pharmaceutical Formulations

The quality and therapeutic efficacy of probiotic formulations are evaluated using physicochemical, microbiological, and biological parameters. Important evaluation methods include probiotic viability (CFU count), encapsulation efficiency, particle size, zeta potential, moisture content, stability studies, in vitro gastric and intestinal survival, drug release profile, mucoadhesion, and shelf-life assessment. In vivo animal studies and clinical trials further assess safety, intestinal colonization, immune response, and efficacy against gastrointestinal infections[15].

Table 3. Evaluation Parameters

Parameter	Purpose
Viable cell count (CFU)	Determines probiotic survival
Encapsulation efficiency	Measures probiotic loading
Particle size	Influences stability and release
Zeta potential	Indicates formulation stability
In vitro GI survival	Evaluates resistance to gastric acid and bile salts
Drug release	Determines controlled release behavior
Stability studies	Assesses shelf-life
Clinical evaluation	Confirms safety and therapeutic efficacy

5. Therapeutic Applications

Probiotic-loaded formulations have demonstrated significant benefits in preventing and treating various gastrointestinal disorders, including antibiotic-associated diarrhea, *Clostridioides difficile* infection, *Helicobacter pylori* infection, infectious diarrhea, inflammatory bowel disease, irritable bowel syndrome, and traveler's diarrhea. They restore gut microbiota, inhibit pathogen colonization, strengthen intestinal barrier function, and modulate immune responses, thereby reducing disease severity and recurrence [10].

6. Challenges and Future Perspectives

Major challenges include maintaining probiotic viability during manufacturing and storage, ensuring targeted intestinal delivery, large-scale production, regulatory standardization, and quality control. Future research should focus on nanoencapsulation, synbiotic formulations, personalized probiotics, microbiome-guided therapies, 3D printing of probiotic dosage forms, and artificial intelligence-assisted formulation design to improve therapeutic outcomes [10].

7. Conclusion

Probiotic-loaded pharmaceutical formulations represent a promising approach for the prevention and treatment of gastrointestinal infections. Advanced delivery systems such as microencapsulation, nanoencapsulation, lipid-based carriers, and hydrogels significantly improve probiotic stability, survival, and intestinal delivery. Continued advances in pharmaceutical technology, microbiome research, and precision medicine are expected to facilitate the development of next-generation probiotic formulations with enhanced clinical efficacy and patient outcomes.

Declarations

Ethics Approval and Consent to Participate

Not applicable. This review article is based exclusively on previously published scientific literature and does not involve human participants, animals, or clinical samples.

Consent for Publication

Not applicable.

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Conflict of Interest

The authors declare that they have no competing financial or personal interests that could have influenced the work reported in this manuscript.

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Code Availability

Not applicable.

Ethical Statement

This manuscript is a review article based on published literature and does not require ethical approval.

Declaration on the Use of Artificial Intelligence

Artificial intelligence (AI)-assisted tools were used only to improve language quality and assist in manuscript drafting. The authors critically reviewed, verified, and approved all scientific content and accept full responsibility for the manuscript.

Abbreviations

Abbreviation	Full Form
AAD	Antibiotic-Associated Diarrhea
AI	Artificial Intelligence
CFU	Colony-Forming Unit

GI	Gastrointestinal
IBS	Irritable Bowel Syndrome
IBD	Inflammatory Bowel Disease
IgA	Immunoglobulin A
NLCs	Nanostructured Lipid Carriers
pH	Potential of Hydrogen
ROS	Reactive Oxygen Species
SLNs	Solid Lipid Nanoparticles
WHO	World Health Organization

Microorganisms

Abbreviation	**Scientific Name**
C. difficile	*Clostridioides difficile*
E. coli	*Escherichia coli*
H. pylori	*Helicobacter pylori*
L. acidophilus	*Lactobacillus acidophilus*
L. rhamnosus GG	*Lactobacillus rhamnosus* GG
S. boulardii	*Saccharomyces boulardii*

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