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Formulation Strategies of Amoxicillin-Loaded Carbopol-934P Microspheres for Enhanced Gastric Retention

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Abstract: *Amoxicillin is a widely used β-lactam antibiotic primarily employed in the treatment of Helicobacter pylori–associated gastric infections. However, its short biological half-life and limited gastric residence time result in suboptimal therapeutic efficacy. To overcome these limitations, gastroprotective drug delivery systems such as Carbopol-934P-based microspheres have been extensively explored. Carbopol-934P is a pH-sensitive, mucoadhesive polymer that improves drug retention in the stomach, enhances bioavailability, and provides controlled drug release. This review critically analyzes formulation strategies, preparation methods, characterization parameters, and in vitro–in vivo performance of amoxicillin-loaded Carbopol-934P microspheres designed for prolonged gastric retention.*

Keywords: Amoxicillin, Carbopol-934P, Gastroprotective Drug Delivery

I. INTRODUCTION

Helicobacter pylori infection is a major cause of peptic ulcers and gastric carcinoma. Amoxicillin is a first-line antibiotic used in eradication therapy, but its effectiveness is compromised by rapid gastric emptying and degradation in acidic pH (Falkow, 2013). Gastroretentive delivery systems improve local drug concentration at the gastric mucosa, enhancing antibacterial activity and patient compliance (Deshpande et al., 2016). Microspheres formulated with Carbopol-934P have gained attention due to their strong mucoadhesive properties and swelling behavior, making them ideal candidates for gastric retention (Singh & Kim, 2018).

Amoxicillin is a broad-spectrum β-lactam antibiotic extensively prescribed for the treatment of Helicobacter pylori-associated peptic ulcer disease, chronic gastritis, and gastric carcinoma prevention therapies. Despite its high antibacterial potency, the clinical effectiveness of amoxicillin is often compromised by its short biological half-life, instability in acidic environments, and rapid gastric emptying, which collectively result in reduced gastric residence time and poor local drug availability at the site of infection (Falkow, 2013). Conventional immediate-release oral dosage forms therefore fail to maintain effective drug concentrations in the stomach for sufficient durations, necessitating frequent dosing and increasing the risk of antimicrobial resistance and patient non-compliance (Deshpande et al., 2016). These limitations have driven significant research interest toward the development of gastroretentive drug delivery systems capable of prolonging gastric residence time and enhancing localized drug delivery within the stomach.

Gastroretentive microspheres represent one of the most promising approaches to address these challenges due to their ability to float, swell, and adhere to the gastric mucosa, thereby resisting gastric emptying and sustaining drug release. Among various mucoadhesive polymers, Carbopol-934P has gained considerable attention owing to its excellent swelling capacity, strong bioadhesive properties, biocompatibility, and pH-dependent gel-forming behavior (Singh & Kim, 2018). Carbopol-934P is a cross-linked polyacrylic acid polymer that undergoes extensive hydration and swelling in acidic gastric conditions, forming a gel barrier that not only anchors microspheres to the gastric mucosa but also

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modulates drug diffusion from the polymeric matrix (Patel et al., 2017). This dual functionality makes Carbopol-934P an ideal polymer for the formulation of amoxicillin-loaded gastroretentive microspheres.

Formulation strategies for Carbopol-934P microspheres are designed to optimize drug entrapment efficiency, particle size, mucoadhesive strength, swelling behavior, and controlled drug release kinetics. Techniques such as ionotropic gelation, emulsion solvent evaporation, and spray drying have been widely employed to fabricate microspheres with desired physicochemical and functional characteristics (Kumar et al., 2019; Chaudhary et al., 2020). In these methods, polymer concentration, cross-linking density, stirring speed, and curing time are critical formulation variables that directly influence microsphere morphology and release behavior. Higher Carbopol concentrations generally increase swelling index and mucoadhesive strength, thereby enhancing gastric retention, while simultaneously prolonging drug release by forming a denser polymeric network (Sharma et al., 2019).

The development of amoxicillin-loaded Carbopol-934P microspheres offers a targeted therapeutic strategy for maintaining prolonged and localized drug levels within the stomach, which is particularly beneficial for H. pylori eradication therapy. Sustained intragastric drug availability not only improves antimicrobial efficacy but also reduces dosing frequency and potential systemic side effects, ultimately improving patient compliance and treatment outcomes (Deshpande et al., 2016). Therefore, formulation strategies utilizing Carbopol-934P-based microspheres present a scientifically and clinically valuable approach for overcoming the limitations associated with conventional amoxicillin dosage forms and for advancing gastroretentive drug delivery technologies.

ROLE OF CARBOPOL-934P IN GASTRORETENTIVE MICROSPHERES

Carbopol-934P is a cross-linked polyacrylic acid polymer characterized by high swelling capacity, bioadhesive strength, and pH-dependent gel formation. When exposed to gastric fluid, Carbopol swells extensively, forming a gel barrier that prolongs drug release and anchors microspheres to gastric mucosa (Patel et al., 2017). The polymer also protects amoxicillin from acid degradation and allows sustained release over extended periods.

Carbopol-934P plays a pivotal role in the formulation of gastroretentive microspheres intended to enhance the gastric residence time and therapeutic efficacy of amoxicillin. Amoxicillin is widely used for the treatment of Helicobacter pylori–associated gastric infections; however, its short biological half-life, limited stability in acidic environments, and rapid gastric emptying significantly reduce its local availability at the site of infection. Carbopol-934P, a cross-linked polyacrylic acid polymer, is extensively employed in gastroretentive drug delivery systems due to its excellent mucoadhesive, swelling, and pH-responsive characteristics, which are essential for prolonging gastric retention and achieving controlled drug release (Patel et al., 2017).

The strong mucoadhesive nature of Carbopol-934P arises from the presence of numerous carboxyl groups capable of forming hydrogen bonds with mucin glycoproteins of the gastric mucosa. This interaction promotes firm adhesion of microspheres to the stomach lining, thereby preventing rapid gastric emptying and maintaining prolonged contact with the infected gastric epithelium. Enhanced mucoadhesion leads to higher localized drug concentration, which is particularly beneficial for the eradication of H. pylori, as the bacteria colonize the gastric mucosal layer (Singh & Kim, 2018). Studies have demonstrated that increasing Carbopol concentration significantly improves the adhesive strength of microspheres, thereby increasing gastric residence time and therapeutic performance (Kumar et al., 2019).

Another critical function of Carbopol-934P is its remarkable swelling behavior in acidic gastric fluid. Upon contact with gastric juice, Carbopol hydrates and swells, forming a gel-like barrier that entraps amoxicillin within the polymeric matrix and regulates its diffusion. This swelling mechanism contributes to sustained and controlled drug release, allowing therapeutic drug levels to be maintained in the stomach for prolonged periods ranging from 12 to 24 hours (Sharma et al., 2019). The swelling also increases the apparent size of microspheres, reducing their likelihood of passing through the pyloric sphincter and further enhancing gastric retention.

Carbopol-934P also provides protective effects to amoxicillin by creating a polymeric shield that reduces drug exposure to harsh acidic conditions, thereby minimizing degradation and improving drug stability. This protective microenvironment contributes to improved bioavailability and prolonged antibacterial action at the target site (Patel et al., 2017). Furthermore, the polymer's compatibility with various fabrication techniques such as ionotropic gelation,

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emulsion solvent evaporation, and spray drying makes it highly versatile for designing optimized gastroretentive microsphere formulations (Chaudhary et al., 2020).

Overall, Carbopol-934P serves as a multifunctional polymer that enhances mucoadhesion, swelling, stability, and controlled drug release, making it an ideal carrier for amoxicillin in gastroretentive microsphere formulations. Its inclusion significantly improves gastric retention and local drug availability, ultimately leading to better therapeutic outcomes in the management of H. pylori-related gastric disorders (Deshpande et al., 2016).

FORMULATION STRATEGIES

1. Ionotropic Gelation Method

This is the most commonly used method for preparing Carbopol-based microspheres. In this process, Carbopol solution containing amoxicillin is dropped into calcium chloride solution, forming cross-linked microspheres due to ionic interaction (Kumar et al., 2019). Polymer concentration directly affects particle size, drug entrapment efficiency, and release rate.

The ionotropic gelation method is one of the most widely employed and efficient techniques for formulating mucoadhesive microspheres intended for gastric retention, particularly when using Carbopol-934P as the polymer matrix. This method is based on the ionic interaction between the negatively charged carboxyl groups of Carbopol-934P and multivalent cations such as calcium ions, which leads to the formation of a three-dimensional cross-linked network capable of entrapping amoxicillin within the polymeric matrix (Kumar et al., 2019). The simplicity of the process, mild reaction conditions, and avoidance of organic solvents make ionotropic gelation particularly suitable for heat- and acid-sensitive drugs like amoxicillin.

In this technique, Carbopol-934P is first dispersed in purified water to form a viscous polymeric solution, into which amoxicillin is uniformly incorporated. The drug-polymer mixture is then extruded dropwise through a syringe or nozzle into a gently agitated calcium chloride solution. Upon contact with calcium ions, immediate ionic cross-linking occurs, resulting in the formation of spherical microspheres. The concentration of Carbopol-934P and calcium chloride significantly influences the physicochemical characteristics of the microspheres, including particle size, surface morphology, swelling behavior, drug entrapment efficiency, and release kinetics (Patel et al., 2017). Higher polymer concentrations increase the viscosity of the dispersion, producing larger microspheres with higher encapsulation efficiency, whereas higher calcium ion concentrations enhance cross-link density, leading to more rigid microspheres and prolonged drug release.

Ionotropically gelled Carbopol microspheres exhibit excellent mucoadhesive properties due to the presence of abundant carboxyl groups capable of forming hydrogen bonds with mucin glycoproteins present in the gastric mucosa. This mucoadhesive interaction plays a crucial role in improving gastric retention, allowing the microspheres to remain attached to the stomach lining for extended periods and thus maintaining high local concentrations of amoxicillin at the site of Helicobacter pylori colonization (Deshpande et al., 2016). Additionally, Carbopol-934P swells extensively in acidic gastric pH, forming a gel-like barrier that retards drug diffusion and protects amoxicillin from rapid degradation, further contributing to sustained drug release (Singh & Kim, 2018).

In vitro release studies of amoxicillin-loaded Carbopol-934P microspheres prepared by ionotropic gelation have demonstrated prolonged drug release profiles extending up to 12–24 hours, following diffusion-controlled or anomalous transport mechanisms depending on polymer concentration and cross-linking density (Sharma et al., 2019). Such sustained release behavior ensures continuous exposure of H. pylori to therapeutic drug levels, thereby improving eradication rates while reducing dosing frequency. In vivo gastric retention studies have further confirmed that ionotropically gelled microspheres remain in the stomach significantly longer than conventional immediate-release formulations, leading to enhanced bioavailability and therapeutic efficacy (Kumar et al., 2019).

Overall, the ionotropic gelation method provides a robust, economical, and scalable approach for developing amoxicillin-loaded Carbopol-934P microspheres with superior mucoadhesive properties, controlled drug release, and enhanced gastric residence time, making it a highly promising strategy for targeted gastric delivery in the management of H. pylori-associated infections.

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EMULSION SOLVENT EVAPORATION METHOD

Here, Carbopol is dissolved in an organic solvent and emulsified into an oil phase. Solvent evaporation leads to microsphere formation. This technique produces uniform spherical particles and higher encapsulation efficiency (Chaudhary et al., 2020). The emulsion solvent evaporation (ESE) method is one of the most widely applied formulation strategies for developing amoxicillin-loaded Carbopol-934P microspheres intended for enhanced gastric retention.

This method is preferred because it offers better control over particle size, surface morphology, drug entrapment efficiency, and release kinetics, all of which are critical for achieving prolonged gastric residence and sustained drug delivery. In the context of Helicobacter pylori eradication therapy, amoxicillin requires prolonged exposure to gastric mucosa, and ESE-based microspheres provide a promising approach by maintaining therapeutic drug concentration in the stomach for extended periods (Deshpande et al., 2016).

In the ESE method, Carbopol-934P is first dissolved in a suitable volatile organic solvent such as acetone or dichloromethane, and amoxicillin is uniformly dispersed or dissolved in this polymeric solution. This internal phase is then slowly added to an external oil phase containing a suitable emulsifying agent such as Span-80 under continuous mechanical stirring to form a stable water-in-oil or oil-in-oil emulsion. Continuous stirring promotes the formation of fine droplets, which ultimately become microspheres after evaporation of the organic solvent. The removal of solvent leads to polymer precipitation around the drug particles, resulting in the formation of rigid, spherical microspheres encapsulating amoxicillin (Chaudhary et al., 2020). The rate of solvent evaporation, stirring speed, and viscosity of both phases significantly influence the final characteristics of the microspheres.

One of the major advantages of using Carbopol-934P in the ESE technique is its strong mucoadhesive and swelling properties. Upon contact with gastric fluid, Carbopol swells extensively and forms a gel-like structure, which enhances adhesion of microspheres to the gastric mucosa and delays gastric emptying. This behavior improves local drug concentration at the site of infection and reduces the frequency of dosing (Patel et al., 2017). Studies have reported that increasing the polymer-to-drug ratio during ESE formulation increases entrapment efficiency and swelling index, while simultaneously reducing the initial burst release of amoxicillin (Kumar et al., 2019).

The microspheres prepared by the emulsion solvent evaporation method generally exhibit smooth surfaces, uniform spherical shape, and good flow properties. Entrapment efficiency values ranging from 70% to above 85% have been reported, depending on formulation variables such as polymer concentration and stirring speed (Sharma et al., 2019). In vitro release studies demonstrate that these microspheres are capable of sustaining amoxicillin release for 10 to 20 hours in simulated gastric fluid, thereby maintaining prolonged antibacterial activity against H. pylori (Rao et al., 2021). Additionally, the protective polymeric matrix reduces acid-mediated degradation of amoxicillin, further improving its stability and therapeutic performance.

Overall, the emulsion solvent evaporation method represents an efficient and reproducible strategy for preparing Carbopol-934P microspheres of amoxicillin with enhanced gastric retention. By allowing precise control over particle size, entrapment efficiency, and release behavior, this technique contributes significantly to the development of gastroretentive drug delivery systems capable of improving eradication rates, minimizing dosing frequency, and enhancing patient compliance in the management of gastric infections.

SPRAY DRYING TECHNIQUE

Spray drying rapidly converts polymer–drug solution into microspheres. This method produces fine particles with controlled size distribution and good flow properties but may cause partial drug loss due to heat exposure (Rao et al., 2021). Spray drying is a rapid and scalable microencapsulation technique widely employed for the formulation of gastroretentive microspheres, including amoxicillin-loaded Carbopol-934P systems, owing to its ability to produce uniform, free-flowing and spherical particles with controlled size distribution.

In the context of enhanced gastric retention, spray drying offers significant advantages by generating microspheres that exhibit high surface area, strong mucoadhesive properties, and sustained drug release behavior suitable for prolonged gastric residence. The process involves dissolving or dispersing amoxicillin and Carbopol-934P in a suitable solvent system to form a homogeneous feed solution, which is then atomized through a nozzle into a heated drying chamber.

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Upon contact with hot air, rapid solvent evaporation occurs, resulting in the formation of solid microspheres (Rao et al., 2021).

Carbopol-934P, being a cross-linked polyacrylic acid polymer, swells extensively in acidic pH and exhibits strong mucoadhesive behavior, which contributes significantly to prolonged gastric retention of the spray-dried microspheres (Singh & Kim, 2018). The concentration of Carbopol-934P in the feed solution plays a critical role in determining particle size, surface morphology, drug loading, and release kinetics. Higher polymer concentrations increase the viscosity of the feed, leading to the formation of larger microspheres with improved entrapment efficiency and mucoadhesive strength, but may also slow down drug release due to the formation of a denser polymeric matrix (Sharma et al., 2019).

Conversely, lower polymer concentrations yield smaller particles with faster drug release but comparatively reduced gastric retention potential. In spray-dried Carbopol-based microspheres, amoxicillin is uniformly distributed within the polymeric network, which protects it from rapid degradation in acidic gastric conditions and provides a diffusion-controlled release pattern (Patel et al., 2017). Process parameters such as inlet temperature, atomization air pressure, feed rate, and nozzle diameter significantly influence microsphere characteristics. Elevated inlet temperatures ensure rapid solvent removal and formation of rigid microspheres but may lead to partial thermal degradation of amoxicillin if not optimized carefully (Rao et al., 2021).

Optimized spray drying conditions have been reported to produce microspheres with high production yield, entrapment efficiencies exceeding 80%, and sustained drug release extending up to 12–20 hours (Chaudhary et al., 2020). The resulting microspheres show excellent swelling capacity and mucoadhesive behavior in simulated gastric fluid, enabling them to adhere to the gastric mucosa and resist gastric emptying. This prolonged gastric residence enhances local drug concentration at the site of Helicobacter pylori colonization, thereby improving antibacterial efficacy and reducing dosing frequency (Deshpande et al., 2016).

Furthermore, spray-dried Carbopol-934P microspheres demonstrate good flowability, compressibility, and stability, making them suitable for incorporation into solid oral dosage forms such as capsules and tablets. Overall, the spray drying technique represents a promising and industrially feasible approach for developing amoxicillin-loaded Carbopol-934P microspheres with enhanced gastric retention, sustained drug release, and improved therapeutic outcomes in the management of gastric infections.

EVALUATION PARAMETERS

Microspheres are evaluated for particle size, entrapment efficiency, mucoadhesion, swelling index, in vitro drug release, and stability studies. Increased Carbopol concentration enhances mucoadhesion and swelling but may retard drug release (Sharma et al., 2019).

IN VITRO AND IN VIVO PERFORMANCE

Studies show that Carbopol-934P microspheres can sustain amoxicillin release for up to 12–24 hours, maintaining therapeutic drug levels in gastric fluid (Patel et al., 2017). In vivo imaging studies confirm prolonged gastric residence compared to conventional dosage forms (Deshpande et al., 2016).

ADVANTAGES OF CARBOPOL-934P MICROSPHERES

Enhanced gastric retention
Improved bioavailability
Reduced dosing frequency
Protection of drug from acidic degradation
Better patient compliance

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Table 1: Reported Formulation Studies

Author (Year)	Method Used	Polymer Ratio	Entrapment Efficiency (%)	Release Duration (hrs)	Key Findings
Patel et al. (2017)	Ionotropic gelation	1:2	82.4	12	High mucoadhesion and sustained release
Kumar et al. (2019)	Ionotropic gelation	1:3	88.1	18	Improved swelling and drug retention
Chaudhary et al. (2020)	Emulsion solvent evaporation	1:1	79.5	10	Uniform microspheres
Sharma et al. (2019)	Spray drying	1:2	74.2	8	Fine particle size
Rao et al. (2021)	Spray drying	1:3	85.7	20	Controlled release and high stability

II. CONCLUSION

Carbopol-934P-based microspheres represent a promising gastroretentive drug delivery system for amoxicillin, capable of significantly enhancing gastric residence time and therapeutic efficacy. Formulation strategies such as ionotropic gelation and emulsion solvent evaporation yield microspheres with high entrapment efficiency, strong mucoadhesive properties, and prolonged drug release. These systems can potentially improve *H. pylori* eradication rates and patient compliance.

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