RESEARCH PAPER

Next-Generation Proton Pump Inhibitors: Advancements in Nano-formulation Technology

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Received: 16th Dec, 2025; Revised: 8th Feb 2026; Accepted: 12th Feb, 2026; Available Online: 28th Feb, 2026

ABSTRACT

Proton pump inhibitors (PPIs) are widely used medications for treating acid-related stomach disorders. However, limitations like poor water solubility and short duration of action can hinder their effectiveness. Nano-formulation technology offers a revolutionary approach to overcome these limitations. By encapsulating PPIs within nanoscale carriers, researchers can improve drug delivery, enhancing solubility, bioavailability, and targeted delivery to the stomach. This can translate to improved symptom control and potentially reduced dosing frequency. Next-generation PPIs formulated with nanotechnology hold immense promise for revolutionizing the treatment of acid-related stomach disorders. This approach offers the potential for improved therapeutic efficacy, reduced side effects, and potentially broader applications in gastrointestinal care. However, carefully considering regulatory requirements and long-term safety studies is crucial for responsible clinical translation. In this article, we demonstrated how nano-formulation technology can enhance the efficacy of proton pump inhibitors (PPIs) by improving their solubility, bioavailability, and targeted delivery. These advancements promise more effective treatment options for acid-related gastrointestinal disorders.

Keywords: *Proton pump inhibitors (PPIs), nano-formulation, drug delivery, targeted therapy, gastrointestinal disorders*

How to cite this article: Yarra S, Repollu M, Renuka P, Rupa DG, Saniya K, Meghana A, Fugicha GU, Susmitha A, Dharani Y and Chinthaginjala H, Next-Generation Proton Pump Inhibitors: Advancements in Nano- formulation Technology. Int J Drug Deliv Technol. 2026;16(20s): 203-209. DOI: 10.25258/ijddt.16.20s.23

Source of support: Nil.

Conflict of interest: None

1. INTRODUCTION:

Proton pump inhibitors (PPIs) are now a mainstay in the treatment of acid reflux disease (GERD), peptic ulcers, and Zollinger-Ellison syndrome; nevertheless, their short half-life and poor water solubility limit their efficacy (1). These disadvantages can result in less-than-ideal treatment effects and frequently require repeated dosage. On the horizon, though, comes a ground-breaking method called nano-formulation technology. Researchers are opening up a new chapter in PPI therapy by encasing PPIs in nanoscale carriers, which has the potential to get around these obstacles and greatly enhance patient care. New formulations can improve drug solubility and bioavailability, allowing more of the medicine to reach the target site and provide the desired therapeutic impact. This may therefore result in better symptom management and a decrease in the frequency of dosage requirements. Targeted delivery, in which PPIs made with nanotechnology can be made to target the stomach, which is the exact area in which they must act. This tailored strategy has great potential to minimize unwanted effects on other body areas and maybe lower the chance of adverse effects. But that's not where the narrative ends. A wide variety of nanocarriers are used for PPI delivery, each with special qualities and benefits. (2) Consider lipid-based nanocarriers as tiny shuttles that effectively move the PPI that has been encapsulated throughout the body. The realm of polymeric nanoparticles, provides a controlled and prolonged release of the medication, possibly increasing its therapeutic efficacy and decreasing the frequency of dose. Even more intriguing ideas like dendrimers and micelles; each has a special method of encapsulating and delivering

PPIs for the best possible therapeutic outcome. (3)Self-assembling nanocarriers can replace labour-intensive manufacturing procedures. Imagine if these carriers would appear in solution on their own, streamlining the manufacturing process and opening the door to more affordable next-generation PPIs. The fascinating idea of stimulus-responsive carriers, which are made to release their drug load in response to particular stimuli such as temperature, pH, or even light changes. This degree of drug release control has interesting opportunities for

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**Author for Correspondence: haranathriper@gmail.com* precise and targeted administration, optimizing therapeutic efficacy at the preferred site and time. The possibility of co-delivering PPIs and other medications inside the same nanocarrier. This creates opportunities for combination therapy, which may allow for the treatment of complicated gastrointestinal disorders with a single, complementary strategy. The path to clinical use, however, needs to be carefully considered. Through stringent review procedures, we can ensure the safety and effectiveness of these innovative formulations by addressing the critical regulatory factors. The necessity of doing long-term safety research will be examined, highlighting the significance of thoroughly evaluating the possible effects of nanocarriers on the body. This intends to demonstrate the revolutionary potential of nano-formulation technology in creating next-generation PPIs by thoroughly examining these aspects. With so much potential to improve the treatment of stomach illnesses connected to acid reflux, this exciting new era will provide patients with a more efficient, convenient, and maybe safer treatment experience.

1.1. Gastric Acid Secretion Physiology

The pharmacodynamics and kinetics of PPIs are closely associated with the structure and function of the H^+–K^+ ATPase enzyme responsible for gastric acid secretion in parietal cells

(4). This proton pump creates a steep hydrogen ion gradient by exchanging intracellular H^+ for luminal K^+. In its resting state, the enzyme remains in an inactive tubular vesicle form and becomes activated upon stimulation by ligands such as acetylcholine, histamine, or gastrin. Gastrin stimulates enterochromaffin-like cells to release histamine, which binds to H_2 receptors and activates intracellular messengers like cAMP and calcium, leading to acid secretion (5). Regardless of the stimulus, acid secretion proceeds through a common pathway involving conformational changes in the H^+–K^+ ATPase, allowing the exchange of H^+ and K^+ ions (6). Upon activation, MgATP provides energy for the enzyme to move to the apical membrane, where proton transport occurs through E1 and E2 conformational states (7). Potassium recycling is maintained via the KCNQ1 channel, which remains active in the acidic gastric environment (8–11). Additionally, bicarbonate (HCO_3^-) is secreted basolaterally to maintain cellular electroneutrality and prevent intracellular acidification (12).

1.1.1. H+-K+-ATPase Enzyme Structure: Parietal Cell Proton Pump

The H^+–K^+ ATPase must be activated at the microvilli for PPIs to bind and inhibit its activity, making its structure critical for drug action (13). This enzyme belongs to the P2 family of ATPases and functions as a heterodimer composed of α and β subunits, similar to Na^+–K^+ ATPase. The α-subunit contains 1,033 amino acids with ten transmembrane segments, where TM4–6 and TM8 form the ion-binding domain. It is highly conserved across species (14). The β-subunit, consisting of about 190 amino acids, has a single transmembrane segment and multiple glycosylation sites essential for structural stability and conformational changes.

PPIs interact with specific cysteine (CYS) residues within the enzyme, with up to ten of the twenty-eight sites involved in binding (15). Key residues such as CYS892 are located on the luminal surface, while others like CYS321, 813, and 822 are within the proton transport region. These binding sites influence the pharmacodynamics and reversibility of PPI action.

1.1.2. Proton Pump Inhibitors (PPIs) Are Activated to Bind to the H-K-ATPase

PPIs must be activated to bind to the ATPase's CYSs, and the rate of activation varies according to the PPIs' structural makeup. (16)These PPIs must be coated with an enteric coating to withstand the breakdown brought on by stomach acid and facilitate absorption in the more alkaline environment of the small intestine because they are weak bases that are labile to acid. The PPIs that are now approved share strikingly similar basic structures, connecting a benzimidazole ring with a pyridine ring through a sulfinyl bond. Timoprazole was discovered to be the first PPI(17); Timoprazole had no changes to these rings, in contrast to the PPIs that are now approved, which contain various substitutions that change their chemical makeup. The sulfinyl needs energy from the parietal cell's acidic environment to chemically bond to the ATPase's CYSs. The PPI is activated by adding two protons to each of the nitrogens on each side of the sulfinyl group. Upon activation, the PPI can create disulfide bonds with the CYS molecules on the ATPase, which deactivates the proton pump. Two values of the pKa (negative logarithm of the acid ionization constant) affect the activation of the PPIs(18). The parietal cell canaliculus's acidic region, where acid is secreted, experiences ionization and accumulation due to the initial pKa, which has a pH of about 1.0. It falls between 3.83 to 4.53. The cytoplasm of this cell is the most acidic in the body. The second pKa of approved medications ranges from 0.11 to 0.79. The sulfinyl is rearranged into a sulfenamide or a cationic sulfonic acid following the second protonation of the benzimidazole. (19). These compounds then have the energy to react with the cysteine sulfhydryls to produce one or more covalent disulfide bonds. On the proton pump, the PPI can attach to multiple distinct CYSs(20). Depending on the speed at which these two activation events occur, it will bind to one or more CYSs. CYS813, which is bound by all PPIs and limits proton transfer, is present on the acidic luminal side of the proton transporter. This location is easily accessible to PPIs for binding, as well as to reducing agents such as glutathione and dithiothreitol, which can release the PPI and reactivate the transporter. The CYS is reacted with by PPIs with slower rates of action, such as pantoprazole and tenatoprazole, at position 822, which is located far down the sixth transmembrane segment of the ATPase. The disulfide bonds that the PPI generates permanently render the proton pump inert because CYS822 is relatively inaccessible to reducing agents. (21). Some of the dynamic variations between PPIs with reversible binding and those that are inaccessible to disulfide bond breakdown can be explained by this difference in binding locations. For the PPI to undergo the above-described acidic activation, it must first reach the parietal cell's acidic site of action while the proton pump is still functioning. Only then can the proton pump be inactivated. The PPI's pharmacokinetics—which start with inert absorption, distribution, metabolism by cytochrome P450 (CYP) 2C19 or CYP3A4, and eliminationdetermine the concentration at the site of action. Predicting the rate of metabolism accurately is complicated by the fact that it is both genetically and developmental controlled.Proton pump inhibitors (PPIs) are now a standard in the management and avoidance of several stomach illnesses linked to acid reflux(22). Their efficacy stems from their capacity to drastically lower the production of stomach acid.

1.2. Mechanism of Action: Targeting the Acid Pump

Stomach acid plays a vital role in digestion by aiding in food breakdown and nutrient absorption; however, excessive acid production can lead to harmful gastrointestinal disorders

(23). PPIs exert their therapeutic effect by targeting the final step of acid secretion in the stomach (24). Parietal cells, specialized cells in the gastric lining, are responsible for acid production (25), where the H^+, K^+-ATPase pump—also known as the proton pump—actively transports hydrogen ions into the stomach lumen using energy from ATP hydrolysis (26,27). PPIs act by irreversibly binding to this proton pump, thereby inhibiting proton transport and significantly reducing gastric acid secretion (28). Although slight variations exist in the binding mechanisms among different PPIs, their overall effect remains the same—effective suppression of gastric acid production (29).

1.3. Acid-Related Disorders

PPIs are the standard treatment for various acid-related gastrointestinal disorders. They are effective in managing peptic ulcers, which are lesions in the stomach or duodenal lining, by reducing gastric acidity and promoting healing (30). In gastroesophageal reflux disease (GERD), PPIs decrease acid reflux into the oesophagus, thereby relieving symptoms such as heartburn and chest pain (31,32). They are also essential in the management of Zollinger– Ellison syndrome, a rare condition characterized by excessive gastrin production leading to increased acid secretion (33). Additionally, PPIs help prevent NSAID-induced ulcers by reducing gastric acid levels and protecting the stomach lining from irritation caused by these drugs (34). Overall, by suppressing gastric acid secretion, PPIs effectively alleviate symptoms and facilitate healing in a wide range of gastrointestinal disorders (35).

1.4. Limitations of Conventional PPIs

Although PPIs are highly effective in reducing gastric acid secretion, conventional formulations have several limitations. Poor aqueous solubility leads to inadequate bioavailability, resulting in delayed onset of action and reduced therapeutic efficacy (36). Additionally, their short duration of action often requires multiple daily dosing, which may reduce patient compliance (37). Extensive first-pass metabolism further decreases the amount of active drug available at the target site (38). Moreover, PPIs have the potential for drug–drug interactions, which can alter the absorption or metabolism of co-administered medications, increasing the risk of adverse effects or reduced efficacy (39). These limitations highlight the need for improved PPI formulations to enhance therapeutic outcomes.

2. NANO-FORMULATION TECHNOLOGY FOR PPIs

2.1 Advantages of Nano-Formulation:

The creation of drug delivery systems at the nanoscale, which usually has a size range of 1-100 nanometres, is referred to as nano-formulation technology(40). When it comes to drug distribution, this tiny size has special benefits over traditional formulations. The possible advantages are broken down as follows:

Improved Solubility: A lot of medications, such as PPIs, have a low water solubility, which makes it difficult for the gastrointestinal tract to absorb them. Drug solubility can be greatly increased by nano-formulations through the use of several techniques(41). To improve solubility, the drug may be shielded from the surrounding aqueous environment by being encapsulated within a carrier system. Methods such as particle size reduction can raise the drug particles' surface area, which will improve solubility by enabling interaction with water molecules(42).

Better Bioavailability: Nano-formulations transfer a higher proportion of the active medicine to the site of action by making the drug more soluble and possibly avoiding first-pass metabolism in the liver(43). This results in increased bioavailability, which means that more of the medication reaches its intended target and has a therapeutic impact.

Targeted Delivery: Traditional PPIs affect the body as a whole systemically. Particularly in the stomach, where they might have their acid-suppressive action, nano-formulations provide the possibility of targeted administration. By focusing on specific areas, the medication may have fewer negative effects when it acts in unexpected places. One way to achieve targeted delivery is to affix particular ligands to the surface of the nanocarrier, which can bind to receptors on stomach cells.

Sustained and Controlled Release: Drug-loaded nano-formulations can be engineered to release their cargo in a regulated way over an extended length of time. This can be accomplished in several ways, such as by employing biodegradable polymers that gradually break down and release the medication that has been encapsulated. Reducing the frequency of dose and possibly increasing patient adherence to treatment plans are two benefits that sustained release can provide.

2.3. Limitations

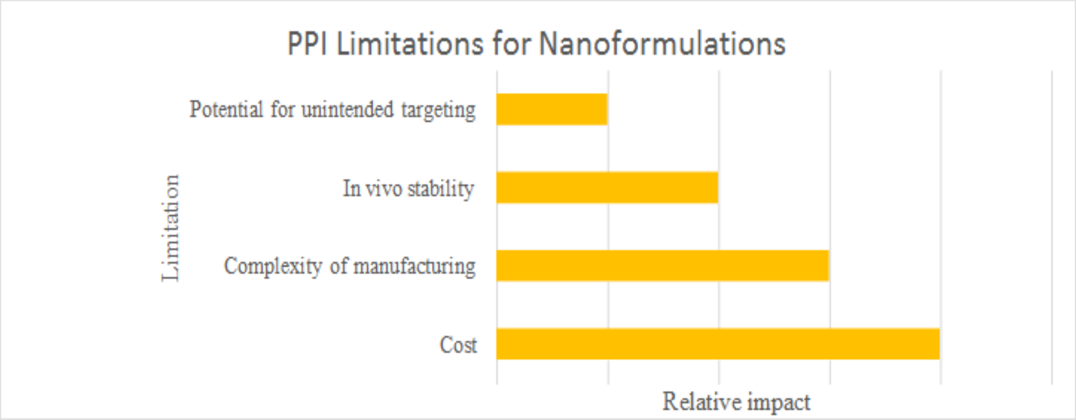

Figure 1: PPI Limitations for Nano-formulations

Overcoming Poor Bioavailability: As was previously mentioned, a significant disadvantage of many PPIs is their poor water solubility. PPIs' solubility can be greatly increased by nano- formulations by the use of strategies including particle size reduction and encapsulation within lipid-based carriers(44). This increased solubility may result in better gastrointestinal absorption and, eventually, increased bioavailability.

Lengthening the Duration of effect: Frequently, the short duration of effect of conventional PPIs requires regular dosage. PPIs can be released gradually and under control using nano- formulations. This can be accomplished by encapsulating the medication in biodegradable polymers, which break down gradually and release the PPI in a regulated fashion(45). By lowering the frequency of doses, sustained-release formulations may increase patient convenience and treatment compliance.

Reducing First-Pass Metabolism: Before conventional PPIs reach their site of action, they may go through a significant amount of liver metabolism. Through a variety of techniques, first-pass metabolism can be circumvented with nano-formulations. It is possible to create nanocarriers that shield the medicine within from hepatic enzymes, thus increasing the amount of active PPI that reaches the stomach(46). Furthermore, some drug formulations have the potential to enable the medicine to be absorbed directly through the lymphatic system, thus avoiding the liver entirely.

Minimizing Drug Interactions: Nano-formulated PPIs may reduce systemic exposure by encouraging localized distribution to the stomach. This focused strategy might lessen the possibility of drug interactions with the patient's other prescriptions.The therapeutic profile of PPIs may be significantly enhanced by these possible advantages of nano-formulated PPIs.

Overall, the distribution of drugs is revolutionized by the technique of nano-formulation. Nano- formulated PPIs have the potential to increase therapeutic efficacy(47), improve patient convenience, and maybe lessen adverse effects by addressing the drawbacks of conventional PPIs, such as poor bioavailability, short duration of action, and possibility for medication interactions.

3. NANOCARRIERS FOR PPI DELIVERY:

The variety of nanocarriers that are used to deliver nano-formulated PPIs is what gives them their potential. With their distinct qualities and benefits, each kind can be used to achieve a range of therapeutic objectives. Now let's examine the four primary types of nanocarriers that are used to deliver PPIs:

Table 1: Characteristics of Nanocarriers for PPI Delivery

Nanocarrier	**Characteristics**
Lipids (e.g., liposomes, SLNs, NLCs)	Biocompatible, biodegradable, improve solubility
Natural/synthetic polymers (e.g., PLGA, chitosan)	Versatile, biodegradable, controlled release, targeting potential
Branched molecules with core and surface groups	High drug loading capacity, multifunctional (targeting, controlled release)
Amphiphilic molecules forming core-shell structure	Self-assembling, core-shell structure for drug encapsulation, improved bioavailability and solubility

3.1. Nanocarriers Based on Lipids:

Lipid-based nanocarriers are composed of naturally occurring lipids and include systems such as liposomes, solid lipid nanoparticles (SLNs), and nanostructured lipid carriers (NLCs) (48). These carriers exhibit excellent biocompatibility and biodegradability, allowing them to be safely absorbed and gradually broken down within the body. They are particularly effective in enhancing the solubility of hydrophobic drugs like PPIs by encapsulating them within lipid matrices. As a result, improved solubility leads to enhanced bioavailability and therapeutic efficacy. Additionally, lipid composition can be modified to achieve controlled drug release and enable targeted delivery to specific regions of the gastrointestinal tract. Witika et al. (2022) further emphasized the effectiveness of lipid-based nanocarriers in improving drug stability, bioavailability, and overall therapeutic outcomes (49).

3.2. Composite Nanoparticles:

Composite nanoparticles are formed using natural or synthetic polymers such as poly (lactic- co-glycolic acid) (PLGA) and chitosan. These systems offer high versatility due to the wide range of polymers available, allowing flexible formulation design. They are biodegradable and can be safely degraded within the body, minimizing long-term accumulation. Additionally, polymeric nanoparticles enable precise control over drug release by modifying polymer composition and formulation parameters, while surface functionalization with specific ligands provides targeted delivery to desired cells. These features allow for sustained and controlled PPI release, improved therapeutic targeting to gastric tissues, and reduced risk of accumulation over time (50). Chen et al. (2021) further demonstrated the effectiveness of composite nanoparticles by developing curcumin-loaded gliadin–rhamnolipid systems, which significantly enhanced solubility, stability, and performance in acidic environments, highlighting their potential in pharmaceutical applications.

3.3. Dendrimers:

Dendrimers are nanosized, highly branched molecules characterized by a well-defined core, multiple branching layers, and terminal functional groups. Their unique architecture provides a high drug-loading capacity, enabling the encapsulation of a large number of drug molecules within their structure. Additionally, their multifunctional surface allows modification with various functional groups, facilitating targeted delivery and controlled drug release. These features make dendrimers suitable for delivering high drug doses in a single carrier while enabling precise control over drug distribution and release. Svenson and Tomalia (2012) highlighted the potential of dendrimers in biomedical applications, particularly for targeted drug delivery, where their tunable surface properties enhance solubility and reduce toxicity, especially in cancer therapy .

3.4. Micellar:

Micelles are nanoscale structures formed by the self-assembly of amphiphilic molecules containing both hydrophilic and hydrophobic regions. In aqueous environments, these molecules spontaneously organize into a core–shell structure, where the hydrophobic core encapsulates poorly soluble drugs such as PPIs, while the hydrophilic shell stabilizes the system. This self-assembly property allows efficient and simple drug encapsulation, enhances drug solubility and bioavailability, and enables surface modification for targeted delivery. Gulia et al. (2023) highlighted advancements in solubilization and gastroretentive systems for PPIs, including floating and mucoadhesive formulations that improve gastric retention, stability, and absorption, thereby enhancing therapeutic efficacy .

4. RECENT ADVANCEMENTS IN NANO-FORMULATED PPIS:

The field of PPIs that are formulated using nanotechnology is always changing as scientists look for new ways to increase their therapeutic potential. An overview of some of the fascinating developments in this field is provided below:

4.1. Self-Composing Carriers of Nanoscale:

The production of conventional nanocarriers can entail costly and time-consuming manufacturing procedures. Self-assembling nanocarriers presents a good substitute. These carriers are made of molecules that, when they come into contact with water, spontaneously assemble into the required nanostructure. As a result, complex manufacturing processes are avoided, which could make the production of nano-formulated PPIs easier and more affordable. As an illustration, some lipids or amphiphilic peptides can be engineered to self-assemble into vesicles or micelles upon dilution in aqueous solutions, encasing PPIs in their center.

4.2. Stimuli-Responsive Nanocarriers:

Conventional nanocarriers typically release drugs passively; however, stimuli-responsive nanocarriers offer a more advanced approach by enabling controlled and targeted drug release in response to specific external triggers such as pH, temperature, or light. These systems allow precise delivery of PPIs at the desired site and time. For instance, pH-responsive nanocarriers release the drug selectively in the acidic gastric environment, thereby reducing systemic exposure and side effects through the use of pH-sensitive polymers . Temperature-responsive systems enable drug release at specific temperature conditions, potentially targeting distinct regions of the gastrointestinal tract . Similarly, light-responsive nanocarriers provide precise spatial and temporal control over drug release by incorporating light-sensitive components that trigger release upon external stimulation .

4.3. Co-delivery of PPIs with Other Medications:

Nano-formulation technology enables co-delivery strategies, where PPIs can be combined with other therapeutic agents such as antibiotics within a single nanocarrier . This approach is particularly beneficial in the treatment of *H. pylori* infections, where simultaneous delivery of a PPI and an antibiotic enhances therapeutic efficacy by targeting both acid suppression and bacterial eradication. Co-encapsulation ensures localized delivery to the stomach, potentially improving treatment outcomes while reducing systemic side effects associated with high antibiotic exposure. Additionally, co-delivery with gastroprotective agents can address both acid suppression and gastric irritation, providing a more comprehensive therapeutic approach. Overall, advancements such as co-delivery systems, stimuli-responsive nanocarriers, and self- assembling technologies highlight the potential of next-generation PPIs to improve efficacy, patient compliance, and safety.

4.4. Types of Nano Formulations:

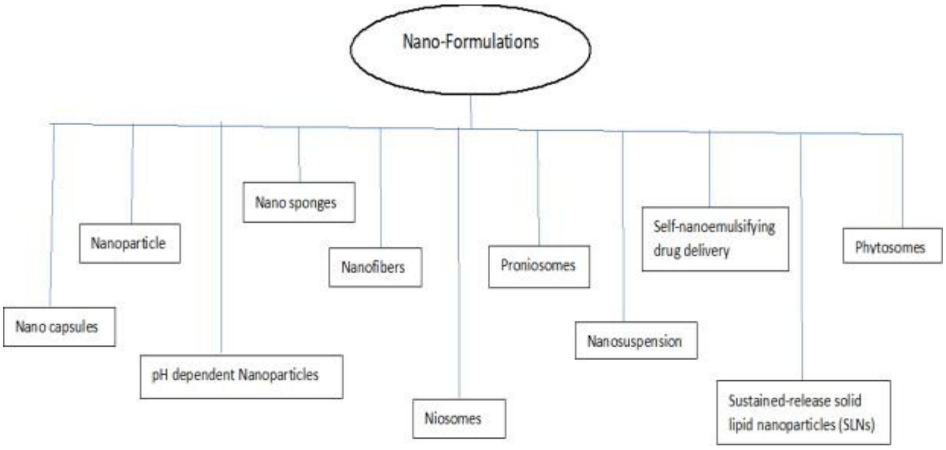

Figure 2: Types of Nano formulations

CONCLUSION

The development of next-generation PPIs driven by nano-formulation technology is expected to bring about a significant change in the management of stomach problems associated with acid reflux. These innovative formulations provide the possibility of better treatment efficacy, increased drug delivery, and maybe decreased adverse effects by resolving the drawbacks of traditional PPIs.

Careful navigation is necessary to make the transition from promising research to therapeutic use. To guarantee the security and effectiveness of these nanomedicines, regulatory obstacles need to be removed. Long-term safety research is essential to comprehending the possible effects of nanocarriers on the human body. But by taking on these obstacles head-on, there's no denying the potential advantages of next-generation PPIs.The wide variety of nanocarriers—from self-assembling marvels to lipid-based shuttles—offers intriguing opportunities for precise and regulated medication delivery. Co-delivery tactics and stimuli-responsive carriers pave the way for even more individualized and cooperative treatments.

In conclusion, a new era in the treatment of acid-related stomach illnesses has begun with the development of next-generation PPIs made possible by nano-formulation technology. For those who are battling chronic ailments, this ground-breaking method holds great potential for enhancing patient care and quality of life and providing a better future. The entire potential of nano-formulated PPIs will surely continue to be realized as research advances, opening the door to a more individualized and efficient approach to gastrointestinal health.

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