

Smart Nano-Insulin Delivery Systems: Possible Route Toward Safer and Physiological Glycemic Control

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ABSTRACT

Diabetes mellitus is still a formidable chronic metabolic disease because of the fact that glycemic levels are always out of control, patient compliance is often poor and conventional subcutaneous insulin treatment cannot achieve the physiological insulin release. In the last few years, nano technology has become a promising platform to improve insulin delivery and insulin stability, insulin bioavailability, controlled release, and targeting insulin to specific tissues. The present review will focus on the recent developments of nano-insulin delivery systems such as polymeric nanoparticles, lipid based nanocarriers, inorganic nanoparticles, hybrid nanocomposites and glucose-responsive smart nanosystems. Of these, glucose-

responsive nanoparticles are a very promising approach, as they can release insulin in response to blood glucose, in turn providing the potential of self-regulated and more physiologically relevant glycemic control. Additionally, targeted nanoparticles and antioxidant-loaded systems provide new opportunities for pancreatic β -cell protection and reduced systemic toxicity. Despite these promising advances, there are significant challenges to clinical translation, such as long-term toxicity, immunogenicity, lack of reproducibility, scalability, storage instability, regulatory uncertainty, and mixed patient response. For future progress to be made, it is essential that future nanosystems are biodegradable, biocompatible and patient-specific, embedded into digital health technologies, artificial intelligence and closed loop insulin delivery platforms. In conclusion, the use of nanotechnology for insulin delivery shows promising potential to revolutionize the treatment of diabetes, but further studies are needed to ensure its safe integration into everyday clinical use, including extensive preclinical testing, standardized testing protocols, and extensive clinical trials.

Keywords: Diabetes Mellitus; Insulin Delivery; Nanotechnology; Glucose-Responsive Nanoparticles; Smart Drug Delivery

Introduction

Diabetes mellitus is a chronic metabolic disorder associated with a metabolic disorder of hyperglycemia, either as a result of defects in insulin secretion, insulin action or both (Duncan et al., 2026; Oltinboyeva et al., 2026). Although insulin formulations have increased, there are still glycemic fluctuations and long-term complications with conventional subcutaneous insulin delivery, which does not mimic the endogenous insulin kinetics (Sánchez-Félix et al., 2020).

Nanotechnology has turned into a foundation for the advancement of innovative stages which can boost proficient medication conveyance (Farghama et al., 2026; Shaffique et al., 2026). Nanoparticles (1-100 nm) possess some special advantages like high drug loading capacity, controlled drug release and tissue targeting (Aslam, Sabri, et al., 2025; Patra et al., 2018; Rafiq et al., 2026). Research has been done to improve the stability, bioavailability and glucose responsive release of insulin by using nanoparticles, which has increased over the past five years (Liu et al., 2024; Umar et al., 2024). Smart glucose responsive nano-insulin systems are critically evaluated in this review, which focuses on the main barriers in the translation process such as long-term safety, manufacturing reproducibility, regulatory requirements, and their inclusion in digital/closed-loop diabetes care, as opposed to previous reviews that broadly summarize the different types of nanocarriers (Chen et al., 2022; Fontana et al., 2025).

Polymeric Nanoparticle for insulin delivery

Much research has been conducted on polymeric nanoparticles, such as poly (lactic-co-glycolic acid) (PLGA) and chitosan, because of their biodegradability and control release properties. Chitosan-based nanoparticles have been shown to open the tight junctions transiently in the intestinal epithelium resulting in paracellular transport and delivery of insulin orally (Wang et al., 2024). But the differences in digestion and absorption of enzymes in gastro tract are still an important problem. While studies

indicated that there was a kick in insulin release from PLGA nanoparticles, sustained insulin release was found in PLGA nanoparticles which might be harmful for the glycemic control (Fonte et al., 2013). Polymeric systems are believed to enhance pharmacokinetics and yet the difficulties in their production and repeatability are a hurdle for clinical use.

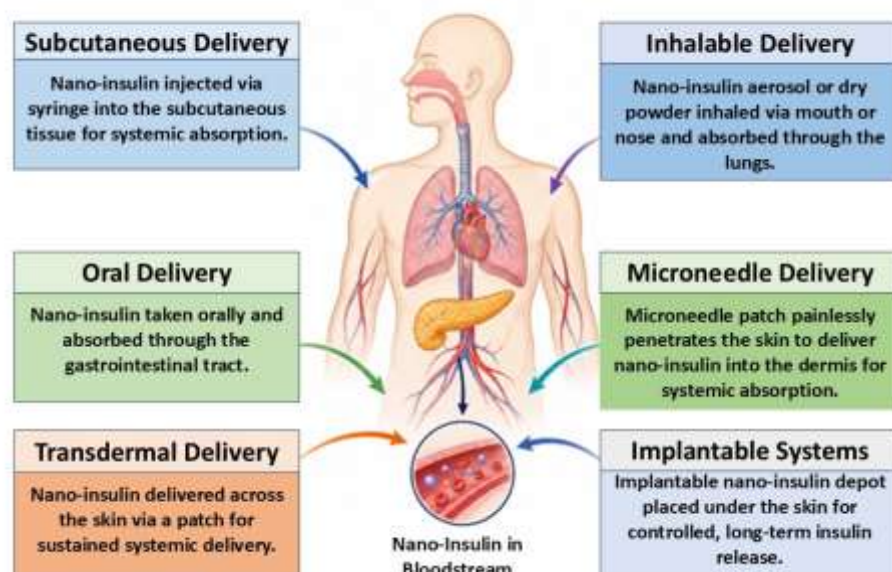


Figure 1 Schematic diagram of nano-insulin delivery routes Subcutaneous, oral, transdermal, inhalable, microneedle, and implantable systems.

Lipid-Based Nanocarriers

Lipid-based nanoparticles such as solid lipid nanoparticles (SLNs) and nanostructured lipid carriers (NLCs) have been recently investigated because of their higher biocompatibility and it has been shown to increase the permeability of the membranes. Lipid nanoparticles have recently been shown to dramatically enhance the bioavailability of oral insulin as they were able to protect the insulin from enzyme degradation and facilitate the uptake of insulin into the lymphatics (Takahashi et al., 2020). But lipid carriers can have a lower drug loading capacity, and can present problems with stability during storage as opposed to polymeric systems. The ultimate point is that, lipid nanoparticles are more patient friendly and, however, do not provide a precise control on the release kinetics and hybrid systems are necessary.

The inorganic nanoparticles

The inorganic nanoparticles and hybrid systems are being studied. The inorganic nanoparticles in particular, such as gold and zinc oxide (ZnO) nanoparticles have several advantages for diabetes treatment. Recently some studies shows improvement in wound healing potential of Cu based nanoparticles (Rafiq et al., 2026) and Co based nanoparticles (Umar et al., 2024). Physiologically there is a role for zinc in insulin production and storage. Jha et al. (2023) have shown that the ZnO nanoparticles also act as a therapeutic agent and delivery vehicle, as they not only improved the glucose uptake of the cells but also improved the insulin sensitivity as

well. Hybrid nanocomposites, a combination of polymeric and inorganic materials is, to date, mostly experimental and are proposed to address these issues. However, clinical applications of inorganic nanoparticles are constrained by concerns for toxicity (Abbas et al., 2025; Aslam, Umar, et al., 2025; Umar et al., 2026a, 2026b).

Glucose-Responsive Nanoparticles: Toward Smart Insulin Systems

One of the major advances in insulin delivery using nanoparticles is the makeup of glucose-responsive systems. These "smart" nanoparticles under hyperglycemic conditions, have glucose sensitive elements such as phenylboronic acid or glucose oxidase (Wang et al., 2024) that will release insulin. These platforms are able to provide better glycemic control than traditional modes of delivery in preclinical models (Pal et al., 2025). However, they are not easily implementable due to their inherent characteristics such as slow response time, low stability and complicated designs (Martínez-Navarrete et al., 2024). The mechanism of glucose-responsive insulin is showing in the figure 2.

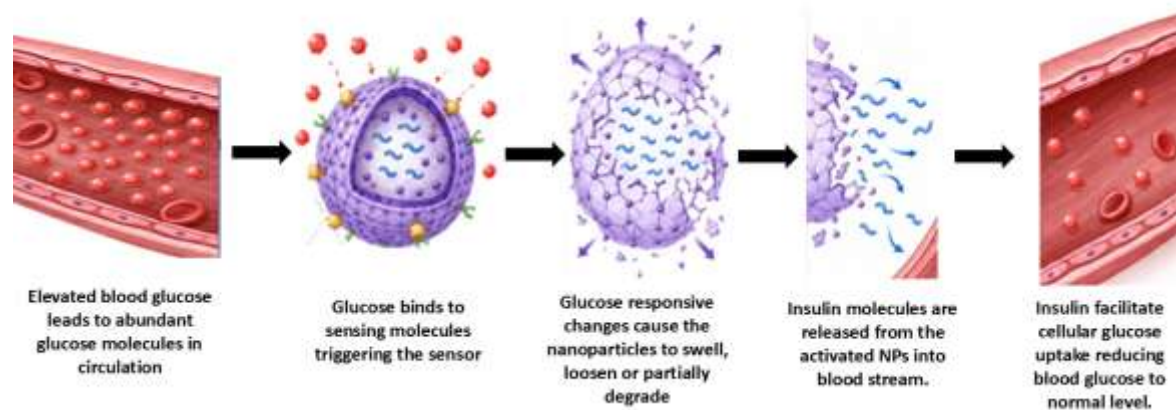


Figure 2 Mechanism of glucose-responsive insulin release

Targeted Delivery & β -cell Protection

Further, the use of nanoparticles as targeted drug delivery systems reduces the systemic exposure and enhance therapeutic activity. Surface-functionalized nanoparticles can be selectively delivered to pancreatic tissues to facilitate the delivery of insulin in the pancreas (Singh et al., 2019). Moreover, antioxidant containing nanoparticles have been shown to reduce the level of oxidative stress, thus protecting the pancreatic β -cells from damage. However, targeting effectiveness and the lack of a unified evaluation procedures are still big research constraints.

Table 1. Types of Nano-Insulin Delivery Systems and their Advantages and Limitations

Type of insulin system	of nano-delivery	Common examples	Major advantages	Major limitations	Translational status / remarks	Key references
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Online ISSN

3007-3197

Print ISSN

3007-3189

<http://amresearchreview.com/index.php/Journal/about>

Polymeric nanoparticles	Chitosan, PLGA, alginate, dextran, PEGylated polymers	Biodegradable; protect insulin from enzymatic degradation; allow controlled/sustained release; chitosan enhances mucoadhesion and intestinal permeability.	Possible burst release; variable drug loading; instability in gastric conditions; oral absorption remains inconsistent; batch-to-batch reproducibility issues.	Among the most widely studied systems for oral insulin delivery, but clinical translation is limited by low and variable bioavailability.	(Fontana et al., 2025; Fonte et al., 2013; Wang et al., 2024)
Chitosan-based nanoparticles	Chitosan-insulin nanoparticles, thiolated chitosan, chitosan-coated PLGA	Strong mucoadhesion; transient opening of epithelial tight junctions; improved paracellular insulin transport; relatively biocompatible.	pH-dependent solubility; enzymatic degradation and mucus turnover may reduce residence time; absorption varies across patients and formulations.	Useful for oral and mucosal insulin delivery, especially when combined with enteric coatings or permeation enhancers.	(Wang et al., 2024)
PLGA nanoparticles	PLGA-insulin nanoparticles, PEG-PLGA, chitosan-coated PLGA	Biodegradable polymer; sustained insulin release; good structural stability; tunable degradation rate; can be surface-modified.	Initial burst release; acidic degradation products may affect insulin stability; optimization of size, charge and loading is complex.	Strong preclinical potential for oral or injectable sustained-release insulin formulations; reproducible manufacturing remains important.	(Fonte et al., 2013; Wang et al., 2024)
Lipid-based nanocarriers	Solid lipid nanoparticles, nanostructured lipid carriers, liposomes, nanoemulsions	High biocompatibility; protect insulin from degradation; enhance membrane permeability and lymphatic uptake; suitable for oral, transdermal and mucosal routes.	Lower insulin loading in some systems; leakage during storage; lipid oxidation; limited precision in release kinetics.	Patient-friendly oral insulin platforms, but formulation stability and long-term storage remain major concerns.	(Fontana et al., 2025; Takahashi et al., 2020)
Inorganic nanoparticles	Gold nanoparticles, silica nanoparticles, zinc oxide nanoparticles, calcium phosphate nanoparticles	High surface-area-to-volume ratio; easy surface functionalization; possible imaging/theranostic use; ZnO may offer additional antidiabetic effects.	Cytotoxicity, oxidative stress, inflammation, poor biodegradability in some systems, and long-term organ accumulation concerns.	Promising experimentally, but direct clinical translation is restricted by biosafety concerns.	(Jha et al., 2023; Patra et al., 2018)

Hybrid nanocomposites	Polymer-lipid hybrids, polymer-inorganic hybrids, lipid-polymer nanoparticles	Combine properties of different materials; improved stability, loading efficiency, controlled release and targeting potential.	Complex formulation; difficult scale-up; multicomponent systems complicate quality control and regulatory evaluation.	High future potential for smart and targeted insulin delivery, but most platforms remain preclinical.	(Fontana et al., 2025; Patra et al., 2018)
Glucose-responsive nanoparticles	Glucose oxidase-based nanoparticles, phenylboronic acid systems, Concanavalin A systems	Self-regulated insulin release in response to glucose concentration; may reduce hypoglycemia risk; better mimics physiological insulin secretion.	Slow response time; limited long-term stability; complex design; possible toxicity from reaction by-products such as H ₂ O ₂ in GOx systems.	One of the most promising smart platforms, but most evidence is still preclinical.	(Liu et al., 2024; Pal et al., 2025)
Nanogel hydrogel-based insulin systems	pH-responsive hydrogels, PBA-functionalized hydrogels, glucose-responsive nanogels	High water content; good biocompatibility; injectable or implantable potential; swelling/degradation can trigger insulin release.	Mechanical weakness; slow diffusion-controlled release; possible in vivo instability; sterilization and storage challenges.	Useful for depot-style or implantable smart insulin delivery; requires improved mechanical stability and faster response.	(Liu et al., 2024; Pal et al., 2025)
Microneedle-assisted nano-insulin systems	Glucose-responsive microneedle patches containing nanoparticles, nanovesicles or hydrogels	Minimally invasive; avoids gastrointestinal degradation; improves patient compliance; enables localized transdermal insulin release.	Limited dose loading; possible skin irritation; patch adhesion and sterilization issues; manufacturing complexity.	Highly attractive for painless smart delivery, but clinical validation is still required.	(Liu et al., 2024; Martínez-Navarrete et al., 2024)
Targeted nano-insulin / beta-cell protective systems	Ligand-functionalized nanoparticles, antioxidant-loaded nanoparticles, pancreas-targeted carriers	May enhance delivery to pancreatic or insulin-sensitive tissues; reduce systemic exposure; antioxidant loading may protect beta-cells from oxidative injury.	In vivo targeting efficiency is difficult to prove; protein corona may alter targeting; lack of standardized targeting-evaluation models.	Promising as adjunctive systems for beta-cell protection and combination therapy.	(Patra et al., 2018)

In general, polymeric and lipid-based nanoparticles are the most widely investigated nano-insulin delivery systems due to their biodegradability, insulin-protective property and their ability for oral or mucosal administration. In contrast, inorganic and

hybrid systems offer further functional benefits, such as surface modification, imaging potential, and enhanced structural stability, with the caveat that clinical translation is limited due to issues of toxicity, accumulation and regulatory complexity. Glucose-responsive nanoparticles, nanogels and systems based on microneedles are interesting emerging platforms that aim to release insulin in response to glucose levels in the blood, which mimics physiological insulin secretion. But, the majority of them still lie at the preclinical level and further studies are needed in terms of long-term biosafety, reproducibility, scalability, storage stability and human clinical validation.

Clinical Translation challenges

Despite many studies in past decade, there are few evidences of the successful transfer of nanoparticle mediated insulin delivery systems from the lab to clinical application. Amongst the most important issues is toxicity and biocompatibility. Despite the fact that many nanocarriers, in particular polymer and lipid based ones, are believed to be biocompatible. But the long-term safety of these has not yet been determined. The long-term toxicity and immunogenic response of nanoparticles are still not fully understood as preclinical studies have revealed that nanoparticles can accumulate in critical organs like liver, spleen and kidney (Patra et al., 2018). In addition, the possibility of oxidative stress and cellular damage is one more problem to the clinical adoption of inorganic nanoparticles, such as zinc oxide or gold nanoparticles. Other major challenges are the scalability of the production of nanoparticles.

The vast majority of the reported nanoparticle systems are made under highly controlled conditions and with fine tuning of the parameters (such as temperature, pH and concentration of reactants). Reproducing these conditions in an industrial manner while maintaining stability, the effectiveness of drug loading and uniformity of the particle size remains a fairly challenging task. A heterogeneity of therapy effects is undesirable in clinical practice, which is also the case for batch-to-batch (Fonte et al., 2013).

There are also major regulatory challenges to be overcome. As a complex system, the nanoparticle-based drug delivery system involves the integration of a wide range of elements from the pharmaceuticals, biological and medical devices sectors and consequently, the regulatory process is more complex than for conventional drugs. So far, there are no detailed and uniform guidelines for nanomedicine imposed by regulatory institutions like FDA and EMA. The uncertainty drives up the clinical translation cost and time, and results in stalling of the approval process (Singh et al., 2019).

The stability and reproducibility are still huge issues. The optimized results of many nanoparticle formulations are lost in in vivo conditions, however, where the structure and functionality of the nanogels are not maintained. The biological environment can significantly impact the properties of nanoparticles, and consequently their drug release profiles and targeting efficiencies, by various factors including protein corona formation, enzymatic degradation and changes in pH (Wang et al., 2024).

Last but not least, patient-dependent parameters (e.g., individual metabolic rate, immunological response and progression of the disease) will hinder translation of the systems based on nanoparticles to deliver insulin. These inter-individual differences are complicating the development of a 'universally successful' nanotherapeutic

platform and it is crucial that specific approaches be taken into consideration for future development.

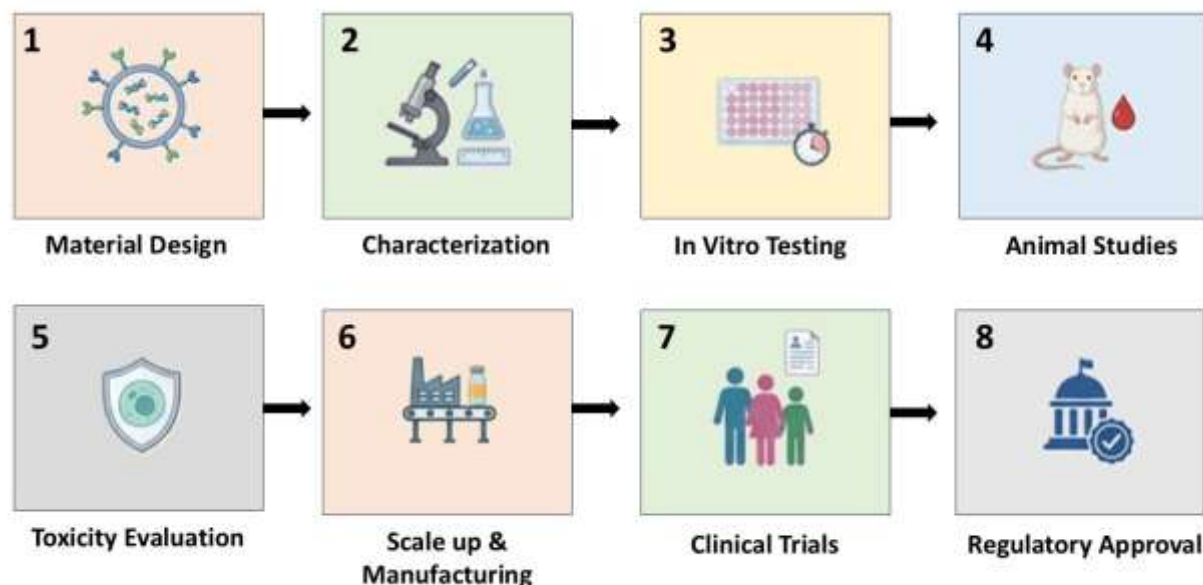


Figure 3 Translational roadmap

Future Perspectives

Smart, tunable and patient specific insulin delivery systems that are able to closely mimic physiological regulation of insulin is the future of nanoparticle insulin therapies. One of the most promising areas is the closed-loop insulin delivery systems, which are also referred to as “artificial pancreas” systems. The designs try to combine CGC with glucose responsive nanoparticles to deliver insulin as per the fluctuating blood glucose level. These methods can greatly help reduce the risk of hypoglycemia and overall glycemic control (Wang et al., 2024).

Another promising research is the development of materials which are completely biodegradable and non-toxic in the form of nanomaterials. Future studies involve decreasing toxicity and trying to create bio-inspired materials, or natural polymers and hybrid materials that have the best features of both organic and inorganic materials. Significant improvement in safety profiles of nanoparticles will also make it easier to accept by patients and get approval from the regulatory authorities and enhance their biodegradability (Patra et al., 2018).

Further improvement of the selectivity of nanoparticles is expected to be achieved by targeted ligands and surface functionalization. The idea is to make use of these advanced techniques to deliver the treatment more efficiently to insulin-sensitive tissues or pancreatic β -cells to reduce the systemic side effects and improve efficacy of the treatment. The challenge of targeting efficiency in vivo is the main one that must be addressed by developing a set of standardized evaluation models (Singh et al., 2019). Moreover, it is expected that AI, digital health platforms and nanotechnology will revolutionize diabetes care. Data-driven models can be used for insulin dosage optimization, glucose trend prediction and for customization of treatment strategy depending on patient profile. Together with the use of the

aforementioned nanotechnology based delivery systems, these technologies have the potential of delivering proper and automated diabetic management.

Despite these encouraging advances, larger-scale clinical trials are still needed to ensure that treatments using nanoparticles of insulin are safe, effective and have long-term benefits. As evidenced by the current literature, there is a significant research-to-clinical translation divide with most research being in vitro and animal studies. To fill this gap, interdisciplinary cooperation between material scientists, physicians, regulatory agencies and the pharmaceutical industry will be required (Fontana et al., 2025). To conclude, although nanoparticle-based insulin therapeutics show great promise, there are still several hurdles in translating the concept to clinical trials, safety and reproducibility issues must be addressed and incorporation of other developing technologies to make insulin delivery truly personalized and responsive is needed.

Conclusion

Insulin delivery using nanoparticles is a highly promising development in the treatment of diabetes that could overcome many of the current challenges of insulin treatment such as enzymatic degradation, low oral bioavailability, the need for frequent injections and non-physiological insulin release. Polymeric and lipid-based nanoparticles have demonstrated great potential for enhancing insulin stability and controlled delivery, while inorganic and hybrid nanosystems offer further therapeutic and targeting benefits. Of the new methods, the glucose responsive nanoparticles are the most promising, as they mimic the way that insulin is released, depending on blood glucose level. The key challenges that hinder the clinical use of these nanosystems to date include their long-term safety, cytotoxicity, immunogenicity, accumulation of nanoparticles, formulation stability, large-scale production, and regulatory approval. Hence, it is essential to design patient-specific and reproducible, biodegradable and nontoxic nanocarriers with better targeting capabilities in future research. The combination of nanotechnology, artificial intelligence, ongoing glucose monitoring, and closed-loop insulin delivery systems could herald a new phase in diabetes care, focused on individualization. To conclude, NPDS is still not ready for mass clinical adoption, but marks a promising and novel trajectory for insulin delivery and therapy to become safer, smarter and more effective in the future.

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