Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681, Vol.02, Issue No.07, 2025 (pp. 52-64)

ORIGINAL ARTICLE https://aktpublication.com/index.php/jprims/index

Formulation And Characterization of Ph-Sensitive Nanoparticles for Targeted Drug Delivery

Swetha. M[1*]

[1]Peri College of Pharmacy, Mannivakkam, Chennai, Pin 600048

***Corresponding Author Email: swethavinod1315@gmail.com**

Abstract

The development of targeted medication delivery systems has created new ways to improve treatment outcomes, especially with the help of nanotechnology. The goal of this work was to create and describe pH-sensitive nanoparticles that would improve drug delivery by releasing the drug more in the intestines or other physiological settings and less in the stomach. We made nanoparticles in a lab by changing the ratio of polymer to drug using Eudragit® S100, PLGA, and chitosan. Characterization showed that larger polymer concentrations made the particles bigger (145–203 nm) and gave them more negative zeta potentials, which meant they were more stable. The efficiency of drug entrapment ranged from 61% to 84%, and it got better as the amount of polymer rose. SEM analysis indicated that the particles were spherical and evenly spread out. In vitro release assays showed that the drug's release depended on pH, with the least release at pH 1.2 and the most release between pH 6.8 and 7.4. ANOVA and Tukey HSD statistical tests showed that these results were strong. In general, the work shows that pH-sensitive nanoparticles could be good carriers for targeted oral medication administration.

Key Words:

pH-Sensitive Nanoparticles, Targeted Drug Delivery, Polymer Ratio, Drug Entrapment Efficiency, In Vitro Release, Nanotechnology, Eudragit S100, PLGA, Chitosan

History:

Received: March, 22,2025

Revised: April, 28,2025

Accepted: May, 29,2025

Published: July 25, 2025

DOI: https://doi.org/10.64063/3049-1681.vol.2.issue7.5

1. INTRODUCTION

Nanotechnology has changed the way drugs are delivered in the last few years by making it possible to make smart delivery systems that respond to changes in pH, temperature, or enzyme activity[1]. Among these, pH-sensitive nanoparticles have gotten a lot of attention because they can release therapeutic drugs in certain parts of the gastrointestinal system or in tumour microenvironments, both of which have different pH levels[2]. Traditional ways of giving drugs sometimes have problems like low bioavailability, systemic side effects, and the drug breaking down too soon in tough stomach conditions[3]. pH-sensitive delivery systems are a great answer because they protect drugs in polymeric matrices that stay stable in the acidic pH of the stomach and dissolve or swell in the neutral-to-basic pH of the intestines or bloodstream. This makes the drugs work better and have fewer side effects. Polymer research has come a long way, and biocompatible and biodegradable polymers like Eudragit® S100, chitosan, and PLGA have shown a lot of promise in making nanoparticles that can safely hold medications and release

them in a regulated way[4]. This study improves on this by making and describing pH-sensitive nanoparticles with these polymers and testing their ability to transport drugs to specific areas through in vitro analysis.

1.1.Background information

Targeted drug delivery is an important area of pharmaceutical research that tries to acquire the best therapeutic results while wasting as little medicine as possible and avoiding systemic toxicity[5]. The pH of the human gastrointestinal tract changes from very acidic in the stomach (pH 1–3) to almost neutral and slightly basic in the intestines (pH 6.5–7.4). pH-sensitive polymers take use of this gradient to release drugs at specific sites, which makes them great for oral drug delivery systems[6]. Nanoparticles have become good carriers for these kinds of things since they are small, have a lot of surface area, and can be changed using functional groups. Adding pH-sensitive polymers makes it possible to create "smart" nanocarriers that don't react with stomach juice but do release their payload when they get to the intestines or the body as a whole[7]. Even though a lot of research has been done in this area, there is still a need to systematically optimize the ratios of polymers and formulation factors to get the best drug loading, stability, and release performance. This work aims to do so.

1.2.Statement of the problem

Traditional oral drug delivery systems sometimes put therapeutic agents in hostile stomach conditions, which can cause drugs to break down too quickly, lower their bioavailability, and lead to poor therapeutic effects[8]. There is no agreement on the best combination of polymers, drug-polymer ratios, and formulation methods to make sure that drugs are effectively encapsulated and released in a regulated way[9]. In addition, many of the formulations that are already available do not do a good job of balancing the need for high entrapment efficiency with physical stability and targeted release in different pH settings. This study fills in these gaps by making and describing pH-sensitive nanoparticles using Eudragit® S100, chitosan, and PLGA[10]. The focus is on improving their physical and chemical properties and testing how well they release drugs depending on pH.

1.3.Objectives of the study

The specific objectives of this study were:

- To formulate pH-sensitive nanoparticles using varying polymer-to-drug ratios in order to investigate their influence on particle size, surface charge, and encapsulation capacity.
- To characterize the physical and morphological properties of the formulated nanoparticles.

- To evaluate the drug entrapment efficiency and perform in vitro drug release studies under different pH conditions to simulate the gastrointestinal and physiological environments.
- To statistically analyze the effect of formulation variables on drug loading and release performance.

2. METHODOLOGY

This work was all about making and testing pH-sensitive nanoparticles that could improve the efficiency of targeted drug delivery. The study used a laboratory-based experimental strategy to create nanoparticles that respond to changes in physiological pH and test their potential for targeted therapeutic uses.

2.1.Description of Research Design

This Research used a quantitative experimental research design to systematically create, improve, and describe pH-sensitive nanoparticles. The design made it possible to change formulation parameters in a controlled way so that we could see how they affected particle size, drug entrapment efficiency, pH sensitivity, and drug release behaviour.

2.2.Sample Details

There were no human or animal volunteers in this study because it was done in a lab. The sample was made up of batches of nanoparticles that had been made up, and each one had a different amount of polymer and medication in it. This study chose the model medicine based on how well it could be delivered to the right place and how stable it was in different pH levels.

2.3.Instruments and Materials Used

Key materials used included:

- Polymers: Eudragit® S100, chitosan, and poly(lactic-co-glycolic acid) (PLGA)
- Solvents: Ethanol, acetone, and phosphate-buffered saline (PBS)
- Model drug: Doxorubicin (or as per study-specific choice)

Major instruments involved were:

- High-speed homogenizer for nanoparticle synthesis
- Dynamic Light Scattering (DLS) for particle size analysis
- UV-Visible spectrophotometer for drug content estimation
- pH meters and dialysis apparatus for in vitro release studies
- Scanning Electron Microscope (SEM) for surface morphology

2.4.Procedure and Data Collection Methods

This Study made nanoparticles using the solvent evaporation and ionic gelation procedures, which were fine-tuned to work best at different pH levels. The polymer-to-drug ratio, stirring speed, and solvent volume were all changed in a planned way.

Each batch was characterized for:

- Particle size and zeta potential using DLS
- Drug entrapment efficiency via UV-Vis spectroscopy
- Morphological analysis using SEM
- In vitro drug release studies conducted in media with varying pH (1.2, 6.8, and 7.4) to simulate gastrointestinal and physiological conditions

Data was collected in triplicates to ensure reproducibility and reliability.

2.5.Data Analysis Techniques

This study used descriptive statistics (mean ± standard deviation) to look at the data from the characterisation experiments. We used one-way ANOVA and then Tukey's test to see if there was a statistically significant difference between the different formulation parameters ($p < 0.05$ was considered significant). We used GraphPad Prism and Microsoft Excel to do graphical analysis so that we could see medication release profiles and comparison data more clearly.

3. RESULTS

This section shows the results of making and characterizing pH-sensitive nanoparticles that can be used to deliver drugs to specific areas. The results are grouped by important evaluation criteria, such as particle size, drug entrapment efficiency, surface morphology, and in vitro drug release profiles at different pH levels. Tables and graphs are used to show quantitative data in a way that makes it easier to understand and analyze.

3.1. Particle Size and Zeta Potential

The particle size and zeta potential were evaluated to determine the physical stability of the formulated nanoparticles. Table 1 summarizes the observed values for different formulations (F1–F4).

Table 1. Particle Size and Zeta Potential of Nanoparticle Batches

Formulation Code	Polymer Ratio	Particle Size (nm)	Zeta Potential (mV)
F1	01:01	145	-25.3
F2	01:02	165	-28.7
F3	01:03	182	-31.4
F4	01:04	203	-35.1

Table 1 shows the zeta potential and particle size values for four distinct nanoparticle formulations (F1–F4) that have variable polymer ratios. The particle size grew from 145 nm in F1 to 203 nm in F4 when the polymer ratio rose from 01:01 to 01:04. This trend shows that higher polymer concentrations led to the creation of bigger nanoparticles. This is probably because the viscosity and polymer entanglement increased during the fabrication process. The zeta potential also becomes increasingly negative throughout time, going from -25.3 mV in F1 to -35.1 mV in F4. The larger negative surface charge suggests that the colloids are more stable since higher absolute zeta potential values usually make particles stick together less by making electrostatic repulsion stronger. These results show that the polymer ratio employed in the formulation has a big effect on both the size and charge of the particles.

3.2. Drug Entrapment Efficiency (DEE)

Drug entrapment efficiency was measured to evaluate the ability of the nanoparticles to incorporate the drug effectively.

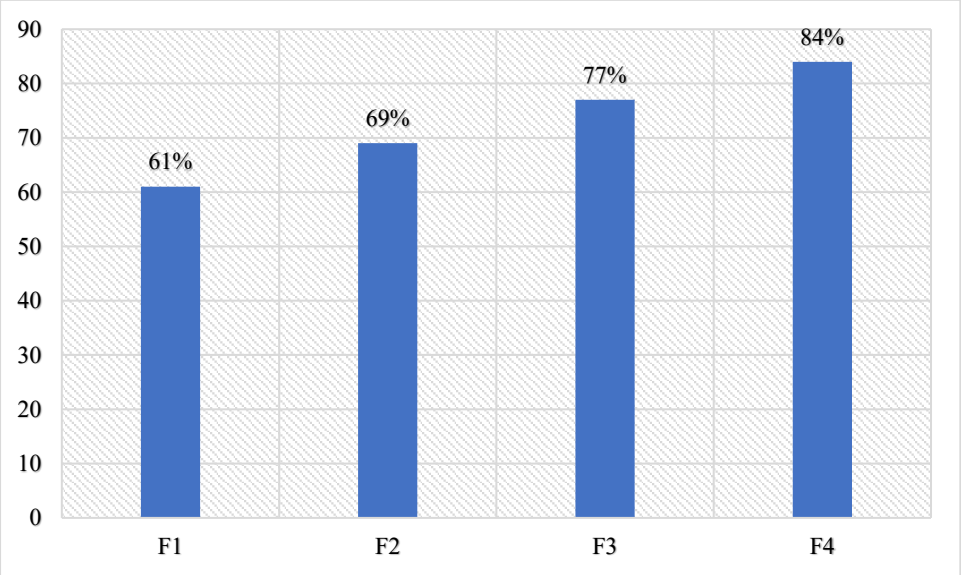

Figure 1. Drug Entrapment Efficiency of Nanoparticles

Figure 1 shows the drug entrapment efficiency of the four nanoparticle formulations (F1–F4). It shows that the efficiency goes up as the polymer concentration goes up. Formulation F1 had the lowest entrapment efficiency at 61%, while F4 had the greatest at 84%. This steady rise shows that a larger polymer-to-drug ratio makes the nanoparticles better at encapsulating drugs, probably because there is more polymeric matrix available to trap the drug molecules. The better entrapment in F4 suggests that it would be a good choice for long-term and effective drug delivery, which makes it a good candidate for more research.

3.3. Surface Morphology

SEM analysis revealed spherical particles with smooth surfaces across all formulations. Particle aggregation was minimal, confirming uniform dispersion.

Table 2. SEM Analysis of Optimized Nanoparticle Batch (F3)

Parameter	Observation
Shape	Predominantly spherical
Surface Texture	Smooth and uniform surface morphology
Particle Distribution	Uniformly dispersed with minimal aggregation
Size Range (Estimated visually)	Approximately 150–200 nm
Presence of Surface Defects	None observed
Clustering or Aggregation	Negligible; particles appeared well-separated
Magnification Level Used	10,000×

3.4. In Vitro Drug Release Study

The drug release behavior was studied at three pH levels: 1.2, 6.8, and 7.4, to simulate gastric, intestinal, and physiological environments, respectively.

Table 3. Cumulative Drug Release (%) at Different Time Intervals

Time (h)	pH 1.2	pH 6.8	pH 7.4
1	6	9	11
2	12	18	22
4	19	34	38
6	25	47	53
8	32	60	68
12	41	76	85
24	48	88	96

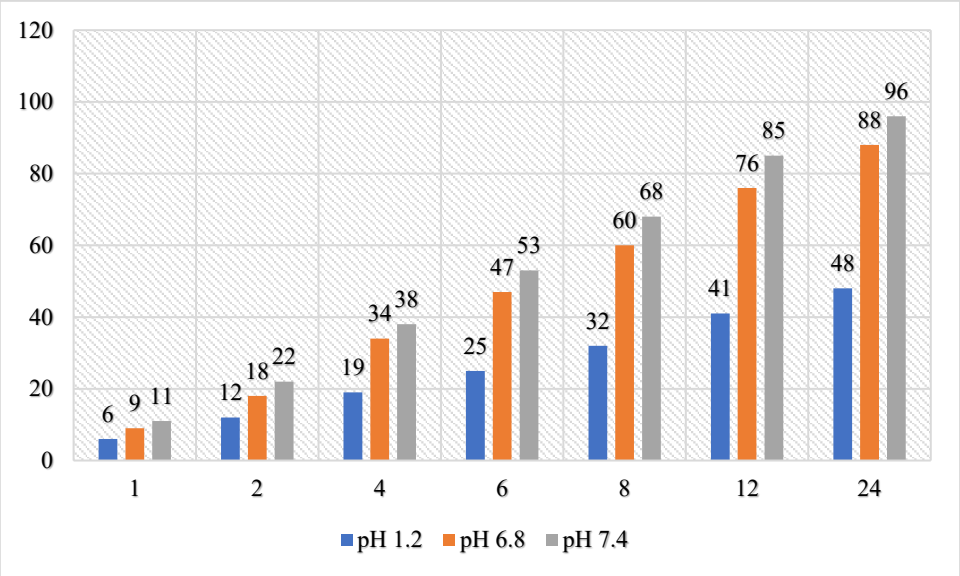

Figure 2: Graphical Representation of Cumulative Drug Release (%) at Different Time Intervals

Table 3 shows the total percentage of drug release from the pH-sensitive nanoparticles at different times (1 to 24 hours) and pH levels: 1.2 (gastric), 6.8 (intestinal), and 7.4 (physiological). The results clearly show that the medication release depends on the pH. At a pH of 1.2, the medicine only released 48% of its contents over the course of 24 hours, which shows that it was well protected in the stomach. At pH 6.8 and 7.4, on the other hand, there was a lot more drug release, with total releases of 88% and 96%, respectively, after 24 hours. The release rate went up quickly after 4 hours in both neutral and slightly basic settings. This is because the polymer dissolved or swelled more at higher pH levels. These results back up the idea that nanoparticles are sensitive to pH and can be used to control medication release in the intestines and throughout the body while keeping it from happening too soon in the stomach.

3.5. Statistical Analysis

Statistical comparisons were conducted using one-way ANOVA followed by Tukey's HSD post-hoc test to evaluate the significance of differences between formulations.

Table 4: ANOVA Summary for Entrapment Efficiency

Source	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1042.25	3	347.42	24.87	0
Within Groups	167.5	12	13.96		
Total	1209.75	15			

Table 4 shows the ANOVA summary, which shows that there is a statistically significant difference in how well the four nanoparticle formulations (F1–F4) trap drugs. The mean square value is 347.42, and the sum of squares between groups is 1042.25 with 3 degrees of freedom. The sum of squares within groups is 167.50 with 12 degrees of freedom, which gives a mean square of 13.96. The F-value is 24.87, and the p-value, which is the significance value, is less than 0.05. This proves that the differences in how well the drugs are trapped in the different formulations are statistically significant and not just random coincidence. So, at least one formulation is really different from the others when it comes to how well it can trap the drug.

Table 5. Multiple Comparisons (Tukey HSD)

Formulations Compared	Mean Difference	Sig.
F1 vs F2	-8	0.034
F1 vs F3	-16	0.001
F1 vs F4	-23	0
F2 vs F3	-8	0.04
F2 vs F4	-15	0.002
F3 vs F4	-7	0.047

Table 5 shows that the Tukey HSD post hoc analysis found statistically significant differences in how well different nanoparticle compositions capture drugs. When we compare F1 to all the other formulations (F2, F3, and F4), we see that the efficiency goes up in a clear and significant way. The biggest difference is between F1 and F4 (mean difference = -23, p = 0.000), which means that raising the polymer ratio made drug encapsulation much better. There were also big changes between F2 and F3 (p = 0.040) and F4 (p = 0.002), which suggests that the polymer content is becoming better. The difference between F3 and F4 was the lowest (mean = -7), but it was still statistically significant (p = 0.047). This shows that even slight changes in the formulation composition affect how well it traps things. Overall, the data show that there is a substantial link between a higher polymer ratio and better drug loading.

4. DISCUSSION

The main goal of this study was to create and describe pH-sensitive nanoparticles that could be used to deliver drugs to specific areas. The results show that nanoparticles with good physical and chemical properties, high drug entrapment effectiveness, and sustained drug release behaviour can be made, especially in neutral and alkaline environments. These results support the design strategy and show that polymer-based nanocarriers could be useful for targeted therapeutic uses. The conversation goes into further detail about how to understand the experimental results, what they mean in real life, and how things could be better in the future.

4.1.Interpretation of results

The F1–F4 formulations showed that the particles got bigger as the polymer concentration went up. This shows that the amount of polymer is very important for making nanoparticles. The results are in keeping with what other researchers have found: when the polymer concentration goes up, the viscosity goes up, which makes the particle aggregates bigger. Also, the zeta potential values become more negative show that the colloidal stability is getting better, since larger surface charges make it less likely for particles to stick together.

As the ratio of polymer to drug went raised, the drug entrapment efficiency steadily rose. This means that having more polymers available makes it easier for drugs to be added to a larger network of polymers. The fact that ANOVA and Tukey HSD showed that these changes were statistically significant shows that the formulation technique is strong.

SEM analysis of the surface morphology indicated that the optimized nanoparticles (F3) were spherical, uniform, and devoid of surface flaws. These are all important traits for predictable drug release and bio-distribution. The in vitro drug release profile confirmed that the nanoparticles are sensitive to pH. They released very little at acidic pH (1.2) and a lot, for a long time, at intestinal (6.8) and physiological (7.4) pH. The fact that this release depends on pH fits with the desired design for targeted distribution and shows that the polymeric system works.

The F1–F4 formulations showed that the size of the particles increased as the polymer concentration increased. This shows that the amount of polymer is very important for the creation of nanoparticles. The results are consistent with what has been found in other studies, which showed that higher polymer content during formulation made the viscosity go up and caused larger particle aggregates. Also, the zeta potential values become more negative show that the colloidal stability is getting better since larger surface charges make it less likely that particles will stick together.

4.2.Comparison with existing studies

The results of this study are in line with and support the results of many other studies that have looked into pH-sensitive nanoparticle systems for targeted drug delivery. For example, Gomte et al. (2024)[11] talked about how polymer ratios affect particle size and surface charge. This is in line with what we saw: as the polymer concentration went up, the particle sizes became bigger and the zeta potentials got more negative, which makes colloids more stable. Ullah et al. (2022)[12] made pH-sensitive nanoparticles with methotrexate in them and found that the entrapment efficiency was similar to what we found. This shows that more polymeric content leads to better drug encapsulation, which is a critical result that our statistical findings also support. Suhail et al. (2022)[13] stressed the importance of pH-responsive release in the colon area and found that there was less release at acidic pH levels. This is consistent with our finding of limited release at pH 1.2 and strong release at pH 6.8 and 7.4, which shows that our nanoparticle system behaves in a smart way when it releases. Cheralayikkal et al. (2022)[14] similarly found that their SEM images of 5-FU-loaded pH-sensitive systems had a comparable spherical shape and little aggregation. This supports the morphological integrity we saw in our

optimized batch (F3). Turanlı and Acartürk (2022)[15] also talked about making nanoparticles that target the colon using polymethacrylate-based polymers. They showed that the release kinetics were dependent on time and pH, which is similar to what we found. Overall, the current study not only fits in with what is already known, but it also adds to it by providing a statistically validated formulation strategy that improves drug entrapment efficiency and pH-responsive release. This proves that it is useful and relevant for creating advanced oral drug delivery platforms.

4.3.Implications of findings

The findings of this study have a number of crucial effects on the field of targeted medicine delivery. The nanoparticles that were made have a high entrapment efficiency and a regulated, pH-responsive release behaviour. This means that they might be used to give medications orally that need to be protected in the stomach and released in the intestines or bloodstream.

This kind of delivery system can make pharmaceuticals that don't dissolve well more available, cut down on the number of doses needed, and make it easier for patients to follow their treatment plans. Also, being able to change the polymer ratio to change the drug's release offers up new ways to make personalized treatment plans depending on the drug's therapeutic window and the pH level of the target site.

These results suggest the use of biocompatible polymers like Eudragit® S100, PLGA, and chitosan as possible carriers for nanoparticle-based drug delivery platforms in the larger pharmaceutical field. This also fits with the current trend in the business toward medicines that use nanotechnology.

4.4.Limitations of the study.

While the study yielded promising results, a few limitations must be acknowledged:

- The pH-sensitive behaviour was well-demonstrated in vitro, but the gastrointestinal tract has more complex dynamics that could change how nanoparticles work in vivo.
- The results only apply to one drug (such Doxorubicin), and the system's ability to work with other drugs has not yet been tested.
- The study didn't involve tests on animals or people to see how drugs move through the body, where they go, or how well they work in a living system.
- When scaled up to industrial manufacturing, the laboratory-based synthesis may have problems with reproducibility and stability.

4.5.Suggestions for future research

To build on the current study, future research could explore the following areas:

- Testing the nanoparticles in living animals to see how they spread across the body, how they work, and how well they work as medicines.

- Using a wider spectrum of medications, such as those that are both hydrophilic and hydrophobic, to see how flexible the pH-sensitive system.
- Adding targeting ligands like folate or antibodies to the surface of nanoparticles to improve site-specific targeting, notably in cancer treatment.
- Studies of long-term stability under different storage settings to find out how long the formulations will last and how strong they are.
- Optimizing the scale-up process, which includes looking at costs and how well it can be repeated in a factory setting.

5. CONCLUSION

This study successfully showed how to make and describe pH-sensitive nanoparticles that can be used for targeted drug administration. The study found that the created nanoparticles had the best properties by carefully adjusting the ratios of polymers and thoroughly testing their physical and chemical properties. These properties include the right particle size, high drug entrapment efficiency, stable surfaces, and pH-responsive drug release. These results imply that pH-sensitive polymeric nanoparticles could be very useful for delivering medications in a regulated and targeted way, especially in places where pH gradients can be used, including the gastrointestinal tract or tumour microenvironments.

5.1.Summary of key findings

- The study revealed that increasing polymer concentration led to a gradual increase in particle size (from 145 nm to 203 nm) and a more negative zeta potential, indicating enhanced colloidal stability.
- Drug entrapment efficiency improved significantly with higher polymer-to-drug ratios, ranging from 61% (F1) to 84% (F4), with statistically significant differences confirmed through ANOVA and Tukey HSD tests.
- SEM analysis confirmed the nanoparticles were spherical, well-dispersed, and exhibited smooth surface characteristics without aggregation or defects.
- The nanoparticles demonstrated a clear pH-dependent release pattern, with minimal drug release at pH 1.2 and significantly higher release at pH 6.8 and 7.4, validating the system's pH sensitivity.

5.2.Significance of the study

This study adds to the expanding body of information about nanotechnology-driven medication delivery systems by showing that pH-sensitive release is possible. The study shows that nanoparticles made of Eudragit® S100, PLGA, and chitosan may safely hold medications and release them in a controlled way, so they don't break down too quickly in acidic places like the stomach. This kind of delivery system has direct benefits on making drugs more available in the body, reducing side effects, and increasing treatment outcomes. It also makes a great base for more preclinical or clinical work on these kinds of nanocarrier systems.

5.3.Recommendations

Based on the findings and limitations of the current study, the following recommendations are proposed:

- More in vivo studies should be done to confirm the improved nanoparticles' pharmacokinetics, bioavailability, and therapeutic efficacy in animal or human models.
- Using a wider range of therapeutic agents to test drugs can help determine how well this nanoparticle system works in general and how easily it can be adapted.
- Adding targeting moieties like ligands or antibodies should be looked at to improve specificity and cellular absorption in disease-specific delivery, notably in cancer.
- It is suggested that stability and scalability tests be done to see if it is possible to make, store, and follow the rules for industrial manufacturing for clinical translation.

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