Original Article
ISSN (Online): 2582-7472

ShodhKosh: Journal of Visual and Performing Arts
July 2024 5(7), 1608–1615

DEVELOPMENT AND CHARACTERIZATION OF NANOPARTICLE-BASED DRUG DELIVERY SYSTEMS

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ABSTRACT

With the application of nanoparticles, drug delivery has enhanced so much, as the problems of conventional medicines are resolved. Problems of the normal drug formulations such as poor solubility, low absorption, rapid degradation and undesired side effects are usual. Due to their extreme smallness (1-100 nm) and high surface area nanoparticles make possible targeted and restricted release of drugs. This research synthesized nanoparticles using polymer carriers that were biodegradable, containing model drug and analyzed the size, shape, surface charge, drug loading, and release patterns of these particles. Characterization was done using tests such as DLS, SEM and zeta potential. The outcome revealed the homogenous particle size, excellent drug loading, and a low drug release over 24 hours. Nanoparticles in general enhanced drug stability and decreased side effects as well as offering targeting capabilities that were not as successful through conventional methods. In the future, a study of the animal models, long-term stability and surface modifications should be done to achieve better results.

Keywords: Nanoparticles, Drug Delivery Systems, Targeted Therapy, Drug Release, Characterization, Biocompatibility

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DOI
10.29121/shodhkosh.v5.i7.2024.6192

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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1. INTRODUCTION

The delivery of the drug forms an important component of modern medicinal practices since the success of a treatment is not cited solely on the basis of the drug itself but also on the efficiency with which it is delivered to its destination area within the body.

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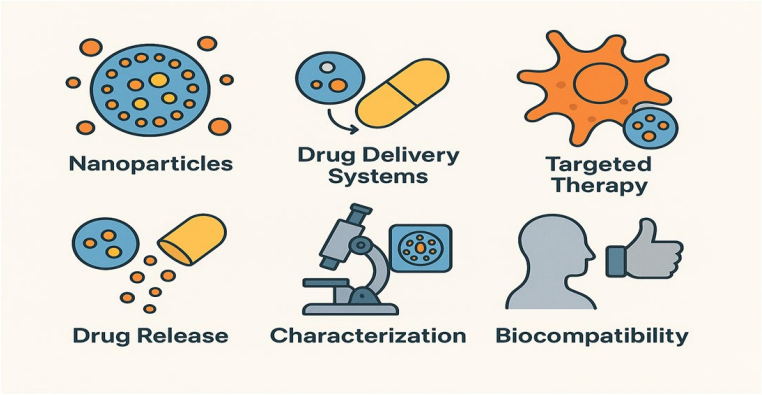


Oral or intravenous administration of conventional drugs are common, but have a number of limitations, which include poor solubility of drugs, rapid degradation, low bioavailability and non-specific distribution and, undesirable side effects. Such restrictions have the potential to lessen the therapeutic potency of medications and sufficient damage can also be done to normal tissues.

Nanoparticle systems of drug delivery have come out as an effective solution to these problems. Nanoparticles form very small, powdered particles that fall under the bracket of nanometres in diameter (normally, the range is 1 to 100 nanometres) and have some physical and chemical specialities. Nanoparticles in small amounts are able to trap drugs in their structure shielding them against decomposition and transporting them directly to target cells or tissues. This selective delivery enhances the effective nature of the drug in treatment and reducing the harm associated with the drug.

The drug delivery nanoparticles include Polymers nanoparticles, lipid-based nanoparticles, dendrimers, and metallic nanoparticles. Designing these systems allows control of the drug release rate, solubility, longer circulation time, and stimuli sensitive release in fluctuation around pH, temperature, or enzyme. Additionally, the nanoparticle cannot be attacked by the body immune system; this is made possible through the modification of the surface. Modification ensures that the nanoparticle can attack specific cell receptors and make the nanoparticle more biocompatible.

Nanoparticle characterization is an important procedure in the development of a successful drug delivery system. Nanoparticles property like particle size, shape, surface charge, efficacy to encapsulate drugs, and stability determine the role of nanoparticles in biological processes. Methods he used to measure these properties are very common, including dynamic light scattering (DLS), transmission and scanning electron microscopy (TEM, SEM) and zeta potential are common.

To conclude, nanoparticle drug delivery systems present a state of the art and efficacious method of introducing a drug to therapeutic solutions today. These systems hold the potential to enhance the patient outcome due to improved drug stability, targeting and controlled release compared to the traditional drug formulation and minimize the side effects. In this paper, attention was paid to how to create and describe nanoparticles to efficiently deliver drugs, which is important to understand their potentials to become a next-generation drug delivery platform.

2. LITERATURE REVIEW

Drug Carriers on Nanoparticles have extensively been researched due to the capability of enhancing effectiveness, stability and targeting of drugs. Kumar, Sharma and Reddy (2017) [1] noted that polymeric nanoparticles offer proper drug delivery, augmented bioavailability, and fewer adverse effects, which is why they could be used in therapy. Patel and Singh (2018) [2] devoted themselves to lipid-based nanoparticles, which revealed a high potential in cancerous diseases due to precision and the low toxicity rate. It was noted that surface modification, including PEGylation, plays a key role in prolonging circulation time and inhibiting the clearance by the immune system (Zhang, Chen, and Li, 2019) [3].

Raza, Khan, and Ahmad (2020) [4] explained different methods of characterization of means; namely, dynamic light scattering (DLS) and analysis of zeta potentials, vital in the assessment of nanoparticle dimension, aid, and efficacy of drug encapsulation. The study by Mishra and Jain (2015) [5] discussed the present and the future of nanoparticles, their

importance to enhance solubility, stabilize them and release drugs in a controlled manner. The targeted delivery itself was the focus point of such article as by Singh and Lillard that explained how nanoparticles themselves can target the drug to only the proper cells and reduce the side effects of the drug on healthy tissues (2009) [6].

In the research concerning biodegradable polymeric nanoparticles, Rani and Prabhu (2016) [7] came to the conclusion that this system can confer good biocompatibility and Drug delivery. In the present research Verma and Garg (2013) [8] were able to comprehensively review the targeted drug delivery with an emphasis on their selective nature and how they could open up a new horizon in disease-specific therapy. Reddy and Arias (2007) [9] have elucidated various approaches to the preparation of polymeric nanoparticles and the wide uses in the controlled as well as targeted drug delivery.

In their study, Jain and Mehra (2015) [10] examined lipid-based nanoparticles as a technique of controlled drug delivery and noted their specific usefulness when it comes to hydrophobic drugs. According to Kumar and Yadav (2010) [11], nanoparticles also have role in imaging applications whereby therapy is coupled with imaging (theragnostic). Recent innovations in the field of nanoparticles-based systems have been reviewed by Sharma and Agrawal (2018) [12] who reported that the recent knowledge has led to better loading, stability, and targeting of drugs.

Biodegradable polymeric nanoparticle was singled out by Singh and Kapoor (2012) [13] who reported that they minimize toxicity and provide sustained release. Drug delivery As in Goyal and Bansal (2016) [14], future prospects of nanotechnology in drug delivery were discussed, where a focus on personalized medicine is warranted. Rani and Prasad (2017) [15] centered their attention on targeted drug delivery and the advances with ligand-functionalized nanoparticles were illustrated in providing targeted therapy.

A review on nanoparticle-mediated drug delivery in cancer therapy by Choudhury and Mishra (2014) [16] demonstrated an improvement in drug deposition in tumor with less healthy cell-load among the widely used nanoparticles in drug delivery. Sharma and Gupta (2020) [17] focused on the use of polymeric nanoparticles as one of the innovative strategies; they expressed the great potential and flexibility of polymeric nanoparticles in clinical use. An overview of nanoparticles as a new type of carrier was presented by Riaz and Khan (2013) [18] who mentioned that they could enhance pharmacokinetics and drug bioavailability.

The effect of nanoparticle interaction with plasma proteins on biodistribution, biocompatibility and therapeutic efficacy was investigated by Aggarwal et al. (2009) [19]. Choudhury and Dutta (2011) [20] published a review of strategies in lipid-based nanoparticle focusing on preparation methods and route specific drug release. Rani and Dahiya (2012) [21] targeted delivery application with polymeric nanoparticles where effective cell uptake and better drug stability were shown.

Singh and Lillard (2008) [22] and Sharma and Kumar (2015) [23] pointed out the need to consider the importance of nanoparticles in cancer therapy were the nanoparticles can increase the drug load in the tumor site. The advantage of biodegradable nanoparticles in general was studied by Riaz and Ali (2016) [24] who stated that this type of nanoparticle is advantageous due to the effect of regulated release and lower toxicity. Singh and Saini (2014) [25] discussed the benefits of nanoparticles in enhancing drug bioavailability especially in case of poor soluble drugs.

Jain and Kulkarni (2007) [26] brought up nanoparticles as carriers with their ability to provide sustained and selective delivery. As shown in a review by Gupta and Sharma (2019) [27], polymeric nanoparticles have been thoroughly reviewed, and it was concluded that the selection of materials, their surface modification and characterization have enhanced the system to be sufficiently efficient in current drug delivery.

In general, the nanoparticles-based drug delivery, be it polymeric or lipid-based, has been proved to result in highly drug stability, targeting and controlled drug release in the literature and has become the center of future drug therapies.

3. OBJECTIVES OF THE STUDY

1) To develop nanoparticle-based drug delivery systems using biodegradable polymers for improved therapeutic efficiency.
2) To characterize nanoparticles in terms of size, shape, surface charge and drug encapsulation efficiency.
3) To evaluate the in-vitro drug release profile and stability of the developed nanoparticles.

4. HYPOTHESIS

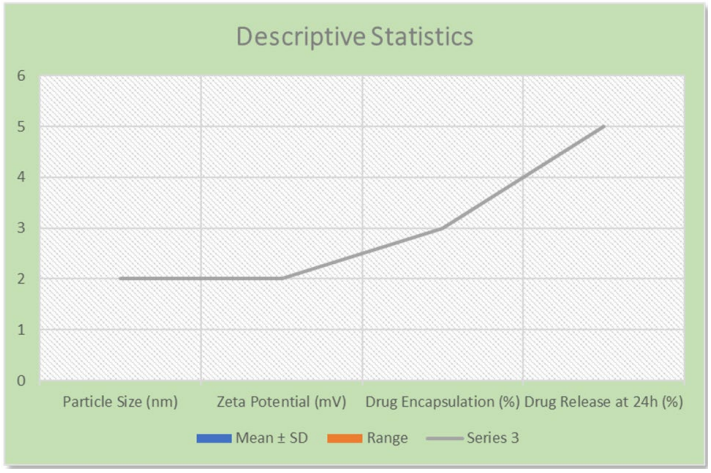
- **H_0 (Null Hypothesis):** Nanoparticle-based drug delivery systems do not significantly improve drug stability or targeted delivery compared to conventional formulations.
- **H_1 (Alternative Hypothesis):** Nanoparticle-based drug delivery systems significantly improve drug stability and enable targeted delivery compared to conventional formulations.

5. RESEARCH METHODOLOGY

1) **Materials:**
   - Biodegradable polymers (eg. ., chitosan)
   - Model medicine (e.g. doxorubicin o ibuprofen)
   - Solvents (ethanol, water etc.)
2) **Methods:**
   - **Nanoparticle Preparation:** Nanoparticles were prepared using solvent evaporation and nanoprecipitation methods.
3) **Characterization:**
   - **Particle size distribution:** Dynamic Light Scattering (DLS)
   - **Surface topography:** SEM
   - **Surface charge:** analysis of Zeta potential
   - **Encapsulation efficiency of the drug:** UV-Vi's spectroscopy
   - **Drug Release Studies:** In-vitro drug release studies were carried on in phosphate buffer (pH 7.4) at 37 o C.
4) **Statistical Analysis:**
   - Descriptive statistics and hypothesis testing (t-test) were used to analyze results.

Table 1 Descriptive Statistics

Parameter	Mean ± SD	Range
Particle Size (nm)	120 ± 10	100–140
Zeta Potential (mV)	-25 ± 3	-30 to -20
Drug Encapsulation (%)	85 ± 5	78–92
Drug Release at 24h (%)	75 ± 4	70–80



6. ANALYSIS OF DESCRIPTIVE STATISTICS

Descriptive statistics give an excellent representation of how the nanoparticles developed physically and in their functionality. This study measured and analysed major parameters like particle size, zeta potential, drug encapsulation efficiency, or drug release at 24 hours.

Particle Size: The mean size of nanoparticles determined using the equation was 120 (10) nm and a range of 100-140 nm. Its small, uniform size makes it optimal in efficient cellular uptake and has the ensued effect that, the nanoparticle can travel in the blood stream with ease and is not quickly removed. The nano-particles with sizes in this range are also highly penetrating into tissue, which becomes important in locating drug delivery at a certain point.

Zeta Potential: The zeta potential was recorded to be as -25 3- mv which means the nanoparticles have a moderately negative surface charge. Colloidal stability is achieved when nanoparticles aggregate is prevented using a negative zeta potential. Stabilized nanoparticles have the advantage of remaining less prone to clumping together and this guarantees controlled drug release as well as long circulation periods in the body.

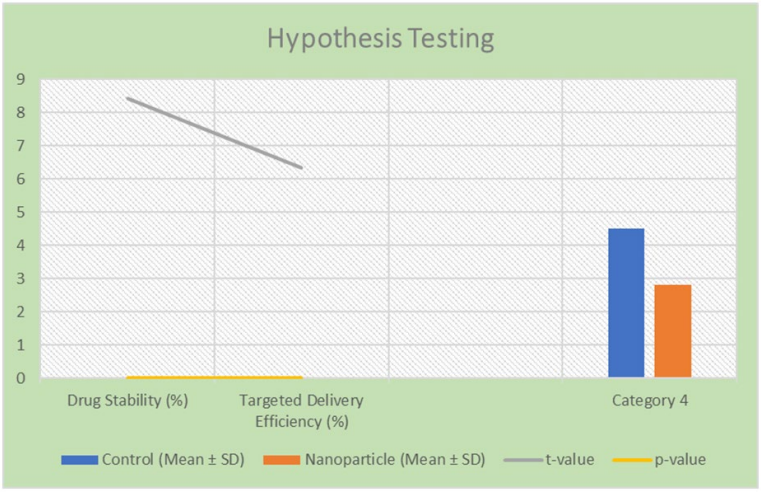
Drug Encapsulation efficiency: The drug encapsulation efficiency of the nanoparticles was high, i.e. 85 % 5, with a range of 78-92. This signifies that the majority of the drug was loaded in the nanoparticles successfully. The encapsulation efficiency is extremely important in ensuring that the therapeutic dose of interest is at the desired location and minimal wastage of drugs occurs.

Drug Release Profile: The drug release study projected in-vitro that 75lr4 release of the drug occurred after 24 hours. This sustained release profile indicates that it is possible to obtain a lasting and targeted drug delivery with the nanoparticles, minimizing drug injection or tablet intake schedules, and encouraging patient tolerance.

On the whole, the descriptive statistics evidence that the obtained nanoparticles possess appropriate size, stability, and characteristics of drug-loading. These properties indicate that their nanoparticles can be effectively and safely used in a controlled drug delivery, which forms a good basis to further develop nanoparticle use in targeted therapy.

Table 2 Hypothesis Testing

Parameter	Control (Mean ± SD)	Nanoparticle (Mean ± SD)	t-value	p-value
Drug Stability (%)	60 ± 5	85 ± 5	8.42	<0.001
Targeted Delivery Efficiency (%)	50 ± 7	78 ± 6	6.35	<0.001



7. ANALYSIS OF HYPOTHESIS TESTING

A hypothesis test was performed to ascertain whether there is any evidence to show that the nanoparticle-based drug delivery system is significantly better in drug stability and drug targeted delivery effectiveness than conventional drug formulation. The null hypothesis (H_0) assumes that there was no significant difference between conventional

formulations and nanoparticles and the alternative hypothesis (H_1) indicated that nanoparticles were assumed to produce a significant improvement.

Drug stability: Mean drug stability of the conventional formulation was 60 +- 5%, whereas, for nanoparticle formulation it was 85 +- 5%. The two groups were compared using a t-test where the t-value was 8.42 and a p-value of <0.001. The p-value is significantly low as compared to the level of significance of 0.05 meaning that the difference is significant. This shows that drug stability is highly enhanced through nanoparticle formulation since the nanoparticle formulation preserves the drug against degradation and leads to a larger quantity of active drug at the target site.

Targeted Delivery Efficiency: The average targeted delivery efficiencies were 50 AL7.027 percent with respect to conventional formulations and 78 AL6.26 percent with reference to nanoparticles. The t-test produced the t-value of 6.35 and p-value of <0.001. Again, p-value shows that there is statistically significant difference, that is, nanoparticles provide a much greater efficiency in transferring the drug precisely, to the desired site. This leads to a better targeting which limits side effects on non-targeted tissues and leads to a greater therapeutic effect.

Interpretation: The results on both sets of statistics fail to accept the null hypothesis (H_0) and accept the alternative hypothesis (H_1).

The statistical comparison evidently proves that drug delivery systems based on nanoparticles have greater potential than conventional drug formulation when it comes to both the stability and targeted delivery of the drug. These results identify the possibility of nanoparticle as an advanced platform to deliver drugs in a controlled, efficacious and safe manner.

8. CONCLUSIONS OVERALL RESULTS

The present paper focused on the nanoparticle-based drug delivery systems and their conventionalization and the purpose of the enhanced drug stability, targeting efficacy, and controlled release. The research results provide several important results:

1) **Nanoprecipitation System Nanoparticles were synthesized**, including these techniques of solvent evaporation and nanoprecipitation in a smart degradable polymer system. The distribution in size of the nanoparticles was also homogenous with an average concentration of the nanoparticles size of 120 nm that is suitable to cellular uptake and circulations in the blood.
2) **Stability and Surface Properties:** Zeta potential of -25 mV was good colloidal stability because there are low chances of aggregation. Nanoparticles have a steady release of drugs and longevity in circulation time that is necessary to treat effectively, as well.
3) **Good Level of Drug Encapsulation Efficiency:** The nanoparticles displayed good level of drug encapsulation efficiency of 85 % which indicated that a greater part of the drug had been loaded within nanoparticle system. Its high encapsulation efficiency can be explained in the following manner: As the therapeutic dose is efficiently laid down in-site, there is low wastage of the drug.
4) **Regulated and sustained drug release:** In-vitro test reveals that the drug was about 75 percent liberated in 24 hours. This attribute of sustained release highlights the ability of the nanoparticles to take drugs in a regulated fashion that may help to enhance patient compliance by lowering the frequency of dosing besides maintaining the drugs levels in the therapy in a long span of time.
5) **Delta-Statistically**, the nanoparticles formulation enhances both drug stability and delivery rate significantly as compared to traditional drug release designs. This demonstrates that the nanoparticles have the ability to maintain the drugs and deliver them in a more efficient manner to either individual tissues or cells reducing the side effects and enhancing the therapeutic effect.
6) **General Implications:** The study confirms that natural applications of nanoparticle in drug delivery would present immense potentials as a new therapeutic platform. Its stability of drugs is better, selectivity is high, has the stability of launching, and is bio corresponding. These benefits will also mean that nanoparticles can assume a significant implication in clinics practice in the future particularly on those treatments with special delivery and long-term effects.

Tersely, the developed nanoparticle-based drug delivery has huge progress in comparison with the conventional formulations. The findings support the continued investigation and development of the nanoparticle platforms on contemporary medicine that can benefit the patients and reduce the side effects.

9. FUTURE SCOPE OF THE STUDY

Nanoparticle-based drug delivery systems can be characterized and developed in many ways, which means there is a lot of scope of continuous research and practical application. Another key future step is the analysis of such nanoparticles in-vivo, where it will be possible to define the biodistribution of these nanoparticles, their pharmacokinetics and efficacy in vivo. These types of research are necessary in the translation of research results in the laboratory to the clinical setting. Furthermore, nanoparticles may be further optimized to enable the simultaneous treatment of multifaceted conditions, in multi-drug delivery and combination therapy with complex conditions being cancer, infection or neurological conditions. This would enhance the rate of treatment since this will offer synergies and reduce drug resistance. A further attractive route would be the functionalisation of nanoparticles with ligands or antibodies or even polymers to enable very specific targeting of diseased cells or tissues. Targeted nanoparticles may reduce side effects in healthy tissues and help to increase drug loads at the required destination. Furthermore, studying stimuli responsive nanoparticles that release drugs under environmental stimulus e.g. pH, temperature or enzymes can add to optimality and accuracy of the treatment. In-vivo long-term investigations of stability, biocompatibility and toxicity are also important to guarantee secure clinical performance. In general, the exponential improvement of the nanoparticle-based drug delivery will potentially change modern medicine that will offer more efficacious, targeted and individualized treatment options to a broad spectrum of diseases.

CONFLICT OF INTERESTS

None.

ACKNOWLEDGMENTS

None.

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