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Letter to Editor

Investigating Pharmaceutical Nanotechnology: Opportunities and Challenges

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With the progress of various sciences, the attention to the nano approach has increased in all fields. Traditional drug delivery methods, despite their use, cannot deliver the drug to the target tissue in a targeted manner. For this reason, the use of a larger amount of the drug causes more side effects [1]. The approach of nanotechnology in targeted drug delivery has received a lot of attention recently and the production of drugs based on nanotechnology worldwide shows its importance [2]. Nanoparticles can be utilized as medication for various ailments or to aid in the targeted delivery of medication within the body [3]. In the last 20 years, 80 nano-pharmaceutical products have been approved by the Food and Drug Administration (FDA), which shows the importance of nanotechnology in pharmaceuticals [4]. Nanotechnology and nano-science are widely perceived as having a significant advantage in various areas of study and applications. Healthcare is already experiencing the impact of nanotechnology because of the development of various nanotechnology ideas and many medicines are based on nanotechnology available on the market [2, 5].

One of the inefficiencies of certain medicines currently available is their poor delivery to the target site. The importance of drug delivery in therapeutics cannot be overstated [6]. An increasing frequency of administration can result in drug toxicity due to misuse, which is one of its drawbacks. Pharmaceutical companies face significant challenges in developing new medicines due to low drug solubility in conventional drug-delivery systems, which can negatively impact efficacy [7]. Colloidal particles with a size range of 1 to 1000 nm are called nanoparticles, and they are mostly made up of different macromolecules that contain therapeutic drugs [8]. Adsorption, entrapment, or covalent attachment can all be used to attach therapeutic drugs [1]. The efficacy of nanoparticles in drug delivery is affected by multiple factors. These include physical and biological stability, good component tolerability, simple manufacturing methods, and ease of production process [7].

Over the last two decades, there has been substantial advancement and development in the utilization of nanotechnology in the field of medicine [8]. The field of nanomedicine has been attained significant attention as it promises to revolutionize medical care therapies that are more efficient, less toxic, and intelligent. They can be used to target the disease site. Nano-sized particles used for drug delivery can be placed in various locations within the body, such as the nose, mouth, skin, eyes, and veins [4]. The blood-brain barrier can be crossed by polymeric nanoparticles and inorganic

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nanoparticles. Nanomedicines will probably consist of three-dimensional structures with multiple components in perfect spatial arrangements. Physicochemical characteristics play a role in how nanoparticles act in vitro and in vivo. The list of aspects that need to be covered include size and size distribution, surface morphology, surface chemistry, surface charge, surface adhesion, steric stabilization, drug loading efficiency, the mechanism by which nanoparticles function, and their impact on blood circulation [8].

Nanomedicine may pose a challenge in identifying the appropriate analytical tests to complete nanoparticle characterization. The manufacturing process may affect the biological components of some proposed nanomedicines, such as proteins or nucleic acids. In some instances, processing may result in compositional changes [4]. Given their intricate nature, a majority of pharmaceutical nanoparticles are composed of various parts arranged most efficiently. To determine the essential characteristics of the product, a comprehensive understanding of the vital components and their interactions is necessary. Employing particular cleaning and sterilization methods can be risky, especially when handling biological materials, due to the potential creation of nanoparticles. This challenge is expected to grow in the future [9]. Nanoparticles can be purified using filters; however, this approach may not be effective for those that can alter their shape, such as liposomes, especially if they are very small (less than 220 nm). For more resilient nanoparticles, including those made of plastic, metal, and silica, filtering might be the sole method available to ensure they are free from germs [10]. Keeping the environment safe is a big concern when making nanoparticles. Tiny particles can move through the air when handling dry materials. These particles can then get stuck in the lungs and cause damage. Tiny particles made in liquid, like how medicine is made, might be better for the environment [11]. Unlike traditional medicine, most pharmaceutical nanoparticles are more complicated because they have multiple parts and structures. This indicates that multiple components of the nanoparticle can influence the effectiveness of the medication within the body. Due to the complexity of nanomedicines, establishing regulations for them may prove challenging [10].

There are no set rules for how to test nanomedicines, because they are different from other types of medicine. The guidelines for these laws differ based on three categories of products: Chemical-based, machine-based, and living organism-based. The FDA has not provided specific instructions for nanomedicines until now because they are considered complex products with many parts. In simple terms, the FDA is not stating with certainty whether nanomedicines are safe. They will look at each product and decide based on its features. In December 2016, the FDA made rules to make it clearer and fairer to decide how to classify and test combination products [12]. The FDA oversees combination products using standard regulations along with additional safety assessments to ensure their efficacy and safety. For example, the FDA has approved new cancer treatments known as paclitaxel and doxorubicin nano-formulations, which are categorized as combination products [12].

The FDA has developed six documents outlining the application of nanotechnology in products it regulates, including nanotechnology-based medicines. These guidelines emphasize that manufacturers should consult with the FDA before marketing their products. Additionally, the European Medicines Agency (EMA) classifies nanomedicines into two categories: Biological and non-biological medicines [13]. A more comprehensive study is required beyond merely measuring the concentration of medicine in the bloodstream for both biological and non-biological nanomedicines. This involves a step-by-step comparison of nanomedicine with conventional medicines, assessing their efficacy, safety, quality, and effectiveness. Such evaluations will help determine whether both types of medicines are equally effective in treating specific conditions. Currently, our understanding of how nanoparticle properties influence their safety and behavior within the body is limited, and traditional animal models may not reliably predict their effects in humans [8].

The impact of nanotechnology on healthcare is beginning to emerge. Over the last twenty years, there has been a notable surge in the development and interest in nanotechnology, which is expected to drive significant advancements in nanomedicines in the future [14]. Consequently, nanomedicine is poised for remarkable growth ahead. Scientists are also investigating alternative applications for nanomedicines to address diseases beyond cancer. To effectively utilize nanomedicines for conditions that are not adequately treated by existing methods, further improvements and innovations will be necessary [15]. To optimize the use of nanoparticles for drug delivery, further research in vitro (test tubes) and in vivo (animal studies) is essential to comprehend how nanoparticles function. This understanding will facilitate the development of effective treatments and ensure they reach those in need. Globally, both governments and businesses are increasing their investments in nanotechnology. The nanomedicine market, valued at USD 138.8 billion, and by 2025, it is projected to hit USD 350.8 bil-

lion. This growth underscores the significance of nanotechnology in medication administration and heralds a new era of drug delivery systems [8].

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