

# Drug Delivery Systems from Bench to Clinical Trials



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## Abstract

The modern nanotechnology has proven its ability to solve most issues associated with drug administrations. Encapsulated drugs can be reached the site of reaction with much controllable. Further, their circulation can be prolonged in blood stream with no dilution for their certain concentration. With these desirable characterizations, drug encapsulation is becoming urgent need for all of medical applications.

**Keywords:** Nanotechnology; Encapsulated drugs; Blood stream; Concentration; Drug encapsulation

## Introduction

Drug delivery nano/micro-systems are widely introduced for preclinical approaches [1]. Many administration methods are represented as oral, local, topical and systemic methods have been approved by Food and drug administration (FDA) [2]. For instance: Gastromark has been approved as clinical imaging applications for oral administration [3]. DepoCyt has been used widely for depot delivery system [4]. Estrasorb has been used clinically for skin penetration [5]. In cancer treatments, Doxil and Abraxane has been represented the majority of all nanoparticle therapies currently in clinical trials. VYEXOS/ CPX-351 is a combination therapy encapsulating a synergistic ratio of two anticancer drugs (cytarabine and daunorubicin) and early clinical results have defined the recommended dose [6] with survival advantages being shown in some patients as compared to standard chemotherapy regimens [7]. there are a number of different paclitaxel or docetaxel micelles currently in clinical trials. The successful preclinical applications of above drug delivery systems are proven great attention, being placed on developing new applications and further improving their delivery and efficacy [8].

Among of these delivery systems, intravenously administered nanoparticles receive the most attention, both preclinically and clinically [8]. However oral routine is still the most accepted methods among these administrations because of its simplicity, convenience, and patient acceptance, especially in the case of repeated dosing for chronic therapy. In this approach, the drug delivery systems functionalized with specific molecules, certain polymers or ligand have been succeed to overcome issue of

acidity of stomach, alkalinity of colon, less circular drug rotation in blood stream, enzymatic degradation and non-targeted selection. Functionalized nanoparticles have proven their ability to overcome rapid blood clearance by the reticuloendothelial system and be able to derive enough amount of chemotherapy or cargo molecules to certain place in term of targeting therapy [9].

Moreover, they can provide protection for healthy cells from side effects resulting from direct reaction with chemotherapies and can offer mechanical support for cargo molecule from engulfment, and dilution [10]. Since drug delivery systems functionalized with polyethylene glycol, can be circulated in blood stream for long time with no recognition by phagocytes or monocytes. Such coatings lead to the formation of hydration shells at the solid/liquid interface which minimize the passage of protein molecules, leading to protein repulsion [11]. The main issue associated with protein adsorption is the subsequent denaturing of the protein, leading to a signaling cascade that results in either aggregation of the nanoparticles and/or phagocytosis via activated macrophages. In the current approach, Hanafy et al. succeed to fabricate drug delivery system based on the fact that polygalacturonic acid is not degraded in the gastrointestinal tract due to its insolubility and hydrophobicity at acidic pH and it could be also insoluble in the colon after its modification [12].

For the above advantages, many therapeutic nanoparticles, imaging agents, and technologies have been approved currently for clinical use, either by the FDA in the United States, or the European Medicines Agency (EMA) in the European Union

[8]. These potential achievements opened the window for investigators and clinical researcher to continue their efforts. From previous publications and investigations, it is being believed that encapsulation cargo molecule at active system should selectively accumulate at site of disease for a prolonged period with high controllability. In our previous work, characterization of curcumin entrapped inside halloysite clay nanotubes was investigated [13]. Finally, the good strategy now is to take advantage of a nanoparticle's control over circulation and bio-distribution for using them in drug encapsulation.

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### References

1. Anselmo AC, Mitragotri S (2014) An overview of clinical and commercial impact of drug delivery systems. *J Control Release* 190: 15-28.
2. Svenson S (2012) Clinical translation of nanomedicines. *Curr Opin Solid State Mater Sci* 16(6): 287-294.
3. Cortajarena AL, Ortega D, Ocampo SM, Gonzalez-García A, Couleaud P, et al. (2014) Engineering iron oxide nanoparticles for clinical settings. *Nanobiomedicine* 1: 2.
4. Min Y, Caster JM, Eblan MJ, Wang AZ (2015) Clinical translation of nanomedicine. *Chem Rev* 115(19): 11147-11190.
5. Hua S (2015) Lipid-based nano-delivery systems for skin delivery of drugs and bioactives. *Front Pharmacol* 6: 219.
6. Feldman EJ, Lancet JE, Kolitz JE, Ritchie EK, Roboz GJ, et al. (2011) First-in-man study of CPX-351: a liposomal carrier containing cytarabine and daunorubicin in a fixed 5:1 molar ratio for the treatment of relapsed and refractory acute myeloid leukemia. *J Clin Oncol* 29(8): 979-985.
7. Cortes JE, Goldberg SL, Feldman EJ, Rizzeri DA, Hogge DE, et al. (2015) Phase II, multicenter, randomized trial of CPX-351 (cytarabine:daunorubicin) liposome injection versus intensive salvage therapy in adults with first relapse AML. *Cancer* 121(2): 234-242.
8. Aaron C. Anselmo Samir Mitragotri (2016) Nanoparticles in the clinic. *Bioengineering & Translational Medicine* 1(1): 10-29.
9. Hanafy NA, Dini L, Citti C, Cannazza G, Leporatti S (2018) Inhibition of Glycolysis by Using a Micro/Nano-Lipid Bromopyruvic Chitosan Carrier as a Promising Tool to Improve Treatment of Hepatocellular Carcinoma. *Nanomaterials (Basel)* 8(1).
10. Hanafy NAN, Quarta A, Di Corato R, Dini L, Nobile C, et al. (2017) Hybrid polymeric-protein nano-carriers (HPPNC) for targeted delivery of TGFβ inhibitors to hepatocellular carcinoma cells. *J Mater Sci Mater Med* 28(8): 120.
11. Hanafy NA, Ferraro MM, Gaballo A, Dini L, Tasco V, et al. (2016) Fabrication and characterization of ALK1fc-loaded fluoro-magnetic nanoparticles for inhibiting TGF β1 in hepatocellular carcinoma. *RSC Adv* 6(54): 48834-48842.
12. Hanafy NAN, Quarta A, Ferraro MM, Dini L, Nobile C, et al. (2018) Polymeric Nano-Micelles as Novel Cargo-Carriers for LY2157299 Liver Cancer Cells Delivery. *Int J Mol Sci* 19(3).
13. Dionisi C, Hanafy N, Nobile C, De Giorgi ML, Rinaldi R, et al. (2016) Halloysite clay nanotubes as carriers for curcumin: characterization and application. *IEEE Transactions on Nanotechnology* 15(5): 720-724.



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