ENGINEERING A CONTROL DRUG RELEASE PROFILE VIA LIPOSOME COMPOSITION IN BOTH AQUEOUS AND NON-AQUEOUS COMPARTMENTS

~~CONTROLLED DRUG RELEASE LIPOSOME COMPOSITION~~

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Application No. 61/792,850, filed March 15, 2013, the entire disclosure of which is incorporated herein by reference.

TECHNOLOGY FIELD

[0002] The present invention relates to a pharmaceutical composition comprising at least one liposome, at least one polyvalent counterion donor or a pharmaceutically acceptable salt thereof, at least one monovalent counterion donor or a pharmaceutically acceptable salt thereof, and a therapeutic agent.

BACKGROUND OF THE INVENTION

[0003] Liposomes have been widely used as an *in vivo* carrier of various therapeutic agents. Ideally, such liposomes should have a high encapsulating efficiency and an extended retention profile (*i.e.* minimal release of the drug before reaching the targeted site).

[0004] NanoVNB® product is a liposomal vinorelbine, which utilizes liposome to enhance the retention of vinorelbine before it reaches the targeted site. Phase I clinical trial of NanoVNB® product did show enhanced anti-cancer efficacy, but the extended retention of vinorelbine *in vivo* also lead to increased toxicity.

[0005] Therefore, there is a need to provide a liposomal composition that is useful for delivery of a therapeutic agent with an adjustable retention profile, to obtain a balance between optimal anti-cancer efficacy and minimal side effect. The present invention addresses this need, as well as other important needs.

BRIEF SUMMARY OF THE INVENTION

[0006] In one embodiment, the present invention is directed to a pharmaceutical composition comprising at least one liposome, at least one polyvalent counterion donor or a pharmaceutically acceptable salt thereof, at least one monovalent counterion donor or a pharmaceutically acceptable salt thereof, and a therapeutic agent, a derivative thereof, or a pharmaceutically acceptable salt thereof. Advantageously, this pharmaceutical composition provides an adjustable retention profile and an adjustable encapsulation percentage of the therapeutic agent.