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Commentary

# A Note on Technology of Drug Delivery System

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## ABOUT THE STUDY

Over the past three decades, significant advances have been made in drug delivery technology. This effort, pioneered by Alxa Laboratories of Palo Alto, Californian among others, has been accelerated in recent years due to a decline in the development of new drug entities. Drug delivery has now become a multidisciplinary science consisting of bio-pharmaceutics and pharmacokinetics. Great strides have also been made by physical biochemists, pharmacists, and other pharmaceutical research scientists working in university and industrial laboratories.

The underlying principle that drug delivery technology, per se. can bring both therapeutic and commercial value to health care products has been widely accepted. Recently, large pharmaceutical companies have been losing their market share to generic competitors with increasing rapidity after their patents expire. This has created an intense need for presenting "old" drugs in new forms and utilizing novel forms of delivery. As a result, companies developing new drug delivery systems seem to enjoy a good return on their investment in the form of increased revenues and market share.

In the United States, the Drug Price Competition and Patent Term Restoration Act (also known as ANDA-Exclusivity Provisions Act) was passed. This provided new incentives to manufacturers who can distinguish their products from competition, with features such as longer dosage schedules, improved safety profiles, new indications for existing drugs and new combinations.

Most efforts to make drug therapy more efficient by direct delivery of drugs to affected tissues have focused on local or regional injection techniques, such as intra-arterial or infusions into body cavities, such as the peritoneum. The benefits of regional therapy include reducing systemic toxicity and achieving peak drug levels directly at the target site. However, these methods of administration have met with limited success. For example, although intro-arterial injections effectively concentrate drugs at certain tumor sites, in others the drug is cleared from the system so rapidly that the benefits are not realized. Currently, pharmaceutical researchers are trying to design drug delivery systems that will localize drugs and affect only the afflicted tissues. A carrier system that has received considerable attention in this regard is liposomes. Emulsions have received somewhat less attention as carriers of therapeutic agents, but they also have the potential for delivery of water-insoluble drugs which will be discussed later.

Liposomes consist of a bilayer of amphipathic lipid molecules (usually phospholipids) encapsulating an aqueous space. The lipid molecules arrange themselves into layers, referred to as lamellae, by exposing their polar head groups toward the water phase. The hydrophobic hydrocarbon "tail" groups adhere together in the bilayer, thus forming close, concentric, bimolecular lipid leaflets separating aqueous compartments. Liposomes vary in charge and size, ranging from 20 rims to 10 µm, depending on the method of preparation and the lipids used. A variety of phospholipids can be used to prepare liposones. The lipid most widely used is phosphatidylcholine (PC), which has been used individually or in combination with cholesterol. Cholesterol is known to condense the packing of phostholipids in bilayers above and modulates the fluidity of the bilayer. Cholesterol reduces the permeability of the bilayers to encapsulated compounds.

Negatively charged lipids such as phosphatidic acid, phosphatidyl glycerol are usually used in order to provide a surface charge to the liposomes. For drug molecules capsulated in the aqueous space the bilayer serves as a diffusion barrier, permitting the liposomes to serve as a rate controlling input device. Papahadjopoulos and workers have done pioneering research in trying to establish and develop the lipomai delivery system from experimental therapeutics to clinical applications. Introduction of this delkery system directly to the target site (such as the eye or bladder) is a well-established approach for treating local diseases, and liposomes have been shown to play a beneficial role when applied in this way. Positively charged lipids such as Stearylamine (STA) can also be used to provide a charge to the lipid bilayer, but these are generally more toxic than negatively charged lipids.

The chemical approach to achieving site-specific delivery requires that the liposome has a targeting I ligand bound to its surface,

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thereby enabling it to attach preferentially to the target site. A variety of targeting ligands have been proposed for this purpose, including antitumor Monoclonal Antibodies (MAb), carbohydrates, vitamins, and transport proteins. Only carbohydrate and MAb-modified liposomes have thus far shown promise in achieving targeting specificity.

Successful targeting of liposomes to cells other than those belonging to the RES is fairly restricted but appears to include hepatocytes and circulating red blood cells. A high degree of specific liposome cell association has been obtained in vitro by coating the vesicles with cell-specific ligands, such as MAbs or F(ab'), fragments. Targeting can also be accomplished by attaching specific peptides folate or other ligands to the liposome surface.