CHAPTER V

CONCLUSIONS

Feasibility of formation of a relatively new class of vesicular drug carriers, niosomes, depends on a variety of factors. These include type of non-ionic surfactants, presence of membrane additives, and method of preparation. The physicochemical properties of the drug to be entrapped are also of importance. This present study focused on effects of formulation factors on feasibility of niosome formation from commonly available non-ionic surfactants. Minoxidil was used as a model for drugs with borderline partition coefficients, which are usually cumbersome to formulate into a vesicular dosage form. Entrapment efficiency (EE) was used as a parameter to indicate effects of formulation and processing factors on the resultant niosomes. The following conclusions can be drawn from the study.

1. It was feasible to prepare niosomes from some commonly available non-ionic surfactants by a method that was devoid the use of organic solvent. These non-ionic surfactants were Span®40, Span®60, and POE-10

2. Cholesterol (CHO) was required in all cases for niosome formation. The appropriate ratio of surfactant to CHO varied with surfactants. The most appropriate compositions for Span®40, Span®60, and POE-10 were at surfactant:CHO ratios of 70:30, 60:40, and 50:50, respectively.

3. Equilibrating time affected EE of niosomes, depending on their membrane compositions. For Span®60:CHO and POE-10:CHO, equililbrium was reached after an overnight equilibrating time. On the contrary, it took Span®40:CHO niosomes five days to reach equilibrium.

4. Feasibility of niosome formation and EE depended on formulation factors, namely total lipid concentration, presence of a stabilizer, and modification of the aqueous phase.

5. It was feasible to from niosomes from Span®40, Span®60, and POE-10 at total lipid concentrations ranging from 50 to 200 mg/mL. Entrapment efficiency, however, decreased as concentration increased in all cases.

6. The two commonly used stabilizers for niosomes, dicetylphosphate (DCP) and Solulan®C24, affected vesucle formation and EE of resultant niosomes. Only the POE-10 surfactant could form niosomes in the presence of DCP, and the EF increased dranatically. Solulan®C24 did not interfere with feasibility of niosome formation. The EE of Span® 60 and POE-10 niosomes increased when Solulan®C24 was included in the formulation. Borderline results, on the other hand, were seen with Span®40 niosomes.

7. Niosomes could not be formed in 30% propylene glycol (PG) in any cases. PG at 15% in the aqueous phase, however, increased the EE of niosomes prepared from all these non-ionic surfactants.

8. Acetate buffer, pH 4.6, allowed formation of niosomes from POE-10 but not from Span®40 or Span®60. The EE of POE-10 niosomes also increased in acetate buffer. Borate buffer, pH 7.0, did not retard niosome formation from these surfactants. The effect on EE was, however, on a case-by case basis. The effect on entrapment increased for Span®60 and POE-10, but the opposite result was seen with Span®40.

9. It was possible to load minoxidil into the blank niosomes by the passive loading method. The EE, however, was lower than the drug was included during the process of vesicle formation. The effect on EE was more apparent with Span®40.

The present study, thus, illustrattes the importance of formulation and processing factors on feasibility of niosome formation and on the EE of the resultant niosomes. These results could be used as a guildeline for pharmaceutical scientists who wish to optimize a niosome delivery system for a drug with a borderline partition coefficient. This study, however, did not establish any relationship between the results seen with the type or structure of non-ionic surfactants due to the limited number of surfactants investigated. Such relationship would better serve the need of most formulations since there are a large variety of non-ionic surfactants to work with. Potential problems with scaling up and stability of the product were not addressed. These issued are necessary for technology transfer to the industry and hence worth further exploring.