CHAPTER 4

AIM AND OBJECTIVE OF THE WORK

4.1 AIM OF THE WORK

The aim of the present investigation was to optimize the two different niosomal formulations containing Rifampicin and Gentamicin Sulphate with respect to formulation and process variables, and evaluate prepared niosomes invitro and invivo for comparing the efficacy against the drug. For this purpose the research envisaged was as follow as:

1. To develop niosomes of Rifampicin and Gentamicin Sulphate, using different ratios of drug : CHOL : Surfactant to prolong the release of drug using lipid film hydration technique.
2. To optimize the prepared niosomes for process variables, namely solvent mixture, sonication time, volume of hydrating media and hydration time.
3. To characterize the prepared niosomes, especially with respect to niosomal size
4. Invitro evaluation of these niosomes for drug release properties.
5. Invivo evaluation of these niosomes on animal model.
6. Pharmacokinetic study of drugs encapsulated niosomes.
7. Stability studies of the potential niosomal products.
8. Evaluation of Results.
9. Summary and conclusion.

4.2 OBJECTIVES OF THE WORK

Rifampicin is a potent inducer of microsomal liver enzymes. Its principal uses are for the treatment of tuberculosis and leprosy. Rifampicin is frequently used as the first line drug in the treatment of tuberculosis. Inspite of this interesting pharmacological profile, after administration, Rifampicin displays a short half life (3.4hr). Tuberculosis is a leading cause of infectious lung disease, requiring a high-dose drug treatment over a period of 4-6 months. Current treatments of tuberculosis are limited by their methods of delivery. Rifampicin also has various side effects such as pruritus, nausea, vomiting and abdominal tenderness and cardiovascular/pulmonary arrest may occur in adults, after a total dose of 14 g.

Gentamicin Sulphate is an aminoglycoside antibiotic, a potent bactericidal agents in vitro, exhibiting a concentration dependent activity. The difficulty of ensuring efficient concentrations in bronchial secretions without inducing systemic adverse effects may lead to clinical failure. Gentamicin Sulphate displays a very short half life (1-4 hr) and has various side effects such as ototoxicity, nephrotoxicity, and neuromuscular blockade.

Because of the above mentioned adverse Pharmacokinetic properties, for Rifampicin and Gentamicin Sulphate, significant advantage could be gained by the development of controlled delivery devices through which are able to reduce the rapid inactivation of Rifampicin, and Gentamicin Sulphate increasing the beneficial effect with decrease in unwanted systemic side effects.

The surfactant-based vesicles (niosomes) may be regarded either as inexpensive alternatives of non-biological origin to liposomes or perhaps as a carrier system for drug(s) physically similar to liposome in vivo, with particular properties that may be exploited to attain different drug distribution and release characteristics.

With the aim of proposing alternative ways to administer drug(s), the use of niosomes as a carrier system is more stable than liposome that has been described here.