CHAPTER 6

SUMMARY, CONCLUSION AND RECOMMENDATIONS

Being a most delicate organ, delivery of drug to the eye is a challenge for the formulator. Recent trends in ocular drug delivery research are to formulate a delivery system which not only prolongs the residence of system in eye but also helps to lower the elimination of the drug and decrease its side effects. In our study attempts were made to develop nanoparticles of hydrophilic NSAID’s which shows better therapeutic effect than conventional ocular dosage forms. Nanoparticles were prepared by using poly-ε-caprolactone with different surfactants such as tween-80, poloxamer-180 and poly vinyl alcohol by double emulsion solvent evaporation or double emulsion solvent diffusion technique. A $3^2$ full factorial design was used to optimize the formulation. Estimation of drug was done by UV-double beam spectrophotometer. Nanoparticles prepared by double emulsion solvent evaporation were large in size, poly disperse system and entrapped less amount of drug. FTIR and XRD spectra’s reveals that the drug was encapsulated inside the particles and crystallinity of drug was decreased. All the formulation showed controlled release profile of drug when compared to marketed eye drops.

Ketorolac tromethamine being a hydrophilic and low molecular weight compound, preparing nanoparticles with high entrapment is a tough task. To overcome this problem, nanoparticle were prepared by double emulsion solvent diffusion method using ethyl acetate as an organic phase and Ca$^{++}$ as counter ion for drug to decrease its solubility in the external aqueous phase. By this method nanoparticles were successfully prepared with high entrapment and the sterility studies concluded that the method used for preparation of nanoparticles yielded a sterile formulation, if the preparation was carried in hygienic conditions. Anti-inflammatory studies showed that the optimized formulation showed better control of PG-E$_2$ induced ocular inflammation than marketed drops. The DES-D preparation technique described here for the encapsulation of hydrophilic molecule in poly-ε-caprolactone nanoparticles resulted in improved formulation characteristics like increased entrapment efficiency, smaller size, lower size distribution, higher
encapsulation yield and this method can be used for the encapsulation of hydrophilic low molecular weight drugs.

In future the optimized nanoparticles should be further evaluated for their long term stability as per ICH guidelines. After stability studies, one can go for clinical trials to evaluate its effectiveness in controlling the ocular inflammation.