IX. SUMMARY AND CONCLUSION

ACECLOFENAC MICROSPHERES

In the present study, microsphere of Aceclofenac, mean particle size range for all formulation was varied from 613.74 to 869.1 \( \mu \)m, due to change in drug and polymer ratio.

Drug entrapment of all formulation was found in range of 60.14 to 75.12\% w/w and its efficiency slightly decreases with increasing the HPMC content. Angle of repose (<40\(^{\circ}\)) for all formulation showed excellent flowability. Shape of the microsphere was found to be spherical by SEM study. In FTIR study, all characteristic peaks were appeared in microsphere spectra without any remarkable change in the position after successful encapsulation, indicated no chemical interaction and stability of drug during microencapsulation process.

Percent drug release rate of F1, F2, F3 formulations (45.80\%, 66.69\%, 81.89\%) in 12 hours, which is slow and incomplete drug release. F5, F6 formulations showed high release rate (97.85\%, 98.89\%) in 10 hours and F7, F8 formulations showed high release rate (98.20\%, 99.24\%) in 9 hours. The in-vitro release data was applied to various kinetic models to predict the drug release kinetic mechanism. The zero order plots for all formulation were found linear in both dissolution medium. Result shows that, drug release rate may follow zero order mechanism. Higuchi and Peppas plot was found good linear, which indicates diffusion may be the mechanism of drug release and n>0.5, that indicated drug release may follow anomalous diffusion.

In-vivo anti-inflammatory efficacy was studied for F4, using cotton pellet granuloma method. It shown better efficacy compared to standard preparation which can be considered as
SUMMARY AND CONCLUSION

Continuous release of drug from formulation. In stability study, there was no remarkable change in content of F₄ formulation during 45 days in which it was stored at various temperatures.

KETOROLAC TROMETHAMINE MICROSPHERES

The major findings emerged from this study are listed below:

The objective of this study was to investigate the effect of parameters—drug concentration, drug: polymer concentration and pH of TPP solution at various drug: polymer ratio on the preparation of cross linked chitosan microspheres. The cross linked chitosan microspheres thus prepared by varying the formulation parameters were studied for percent yield, average particle size, encapsulated amount of drug and in vitro drug release rates.

The microspheres can control the release, avoid dose dumping, and extend the duration of action of a drug for effective management of pain. The microspheres prepared at laboratory scale, with good batch-to-batch reproducibility with respect to yield, particle size, and % drug entrapment efficiency of microspheres.

FT-IR studies did not reveal any significant drug excipients interactions. After studying various parameters it was observed that highest encapsulated amount of drug and highest percentage drug release was achieved at drug concentration of 1.5% (w/v), chitosan concentration of 1% (w/v) and at pH 9 of TPP solution having concentration 2% (w/v),. Morphology and stability of these microspheres were also good as compared to others at these optimized values. Thus, ionotropic gelation method, a milder and effective method of preparation of microspheres may be used by optimizing various parameters like drug concentration, drug: polymer concentration and pH of TPP solution. Further, other parameters
may also be optimized and studies are to be done extensively so as to achieve an ideal controlled drug delivery system.

The stability study was carried out at room temperature and at 45°C and 75% RH for 45 days. The results showed that, non-significant difference was observed between the release pattern of fresh and stored microspheres. The optimized multiple-unit microspheres delivery system is expected to provide clinicians with a new choice of an economical, safe and more bioavailable formulation.