SUMMARY & CONCLUSION
SUMMARY

In this investigation, colon targeted tablets of FLB (100 mg) and KTM (20 mg) were prepared as matrix and/or compression coated tablets. The tablets prepared using HPMC and SA as time-dependent polymers and ED as pH sensitive polymer for colon targeting. The tablets were characterized to optimize the formulations to achieve the colonic delivery i.e., retardation of drug release in initial lag period (5h) and progressive drug release in a slow manner for 24 h.

**Flurbiprofen Matrix Tablets:**

Considerable effort was put to prepare matrix type colon drug delivery system of FLB using HPMC and SA with acceptable physical characteristics. HPMC matrix tablets are able to protect the drug from upper GIT. From dissolution studies, M11 formulation showed the significant level of FLB colonic release. The drug release from above formulation followed zero order profile and followed supercase II transport.

**Flurbiprofen Compression Coated Tablets:**

This part of investigation was deals to develop new colonic tablets using combined approaches of time-controlled and pH-specific approaches using HPMC and SA as compression coat polymers with and without ED. In this study HPMC-ED compression coated tablets were prepared to retard release in upper GIT to gain colon targeting. All FLB formulations were prepared using HPMC and SA and they showed
acceptable physical characteristics. In above formulations HPMC K4M-Eudragit S100 compression coated tablets were considered as good formulation. Based on dissolution studies, C11 formulation showed significant level of drug release in the colon. They followed zero order release with supercase II transport. DSC and FTIR spectral studies revealed the absence of incompatibility between FLB and excipients and the accelerated stability studies showed stability of FLB in tablet.

The *in vivo* x-ray imaging study in human volunteers showed that C11 formulation tablets arrived colon with no loss of tablet integrity upper GIT. The results of *in vivo* study human volunteers showed that the colon targeted tablets specifically released FLB in large amount in colon with no loss in upper GIT when compared to IR tablets. In conclusion, development of HPMC K4M-Eudragit S100 compression coated tablets (combining pH-sensitive and time-controlled methods) is a good approach to target the FLB in colon.

**Ketorolac Tromethamine Matrix Tablets:**

Matrix type colon drug delivery system of KTM with acceptable physical characteristics was successfully developed using HPMC and SA as matrix forming agents. HPMC matrix tablets are able to overcome the loss of drug in upper GIT to deliver significantly to colon. From dissolution studies, M9 formulation selected as optimized one for specificity. The drug release from above formulation followed zero order profile with supercase II transport.
**Ketorolac Tromethamine Compression Coated Tablets:**

Compression coated colon specific tablets of KTM with using HPMC and SA were developed acceptable physical characteristics. HPMC K4M compression coated tablets are proficient to give retardation of release in upper GIT. From dissolution experiments, C4 formulation demonstrated the significant level of drug release in the colon, that followed zero order profile and the drug release mechanism followed supercase II transport. DSC and FTIR spectral studies explained the absence of interactions between the KTM and excipients and the accelerated stability studies showed stability of tablet.

The *in vivo* x-ray imaging study in human volunteers revealed that C4 formulation tablets arrived colon with no loss of tablet integrity upper GIT. Results of the *in vivo* study human volunteers illustrated that the colonic tablets exclusively released KTM in large amount in colon with no loss in upper GIT when compared to IR tablets. In conclusion, developing HPMC K4M time dependent compression coated tablets is a good approach to colon target the KTM.

From the above results, it was concluded that the HPMC K4M was better time dependent polymer when compared to SA. When compared to matrix tablets compression coated tablets were superior to give specific drug release to colon with less amount of drug release in upper GIT. In comparison of two drugs KTM requires high amount of polymer to give successful colon specific release due to high solubility in nature when
compared to insoluble FLB. In combination with ED, HPMC showed better in colon specific release of FLB.
CONCLUSION

Colon targeted tablets of FLB and KTM were prepared using HPMC and SA as time-dependent polymers and ED as pH sensitive polymer for colon targeting and they were characterized. From the results, it was concluded that the HPMC K4M was better polymer when compared to SA. When compared to matrix tablets compression coated tablets were superior to give colon-specific release of drug with less amount of drug release in upper GIT. In comparison of two drugs KTM requires high amount of polymer to give successful colonic release due to its high solubility when compared to insoluble FLB. The drug release from above formulations followed zero order profile and supercase II transport. DSC and FTIR spectral studies explained the absence of interactions between the drug and excipients and the accelerated stability studies showed stability of tablet. The in vivo x-ray imaging studies in human volunteers showed that the tablets arrived colon with no loss of tablet integrity upper GIT. The results of in vivo pharmacokinetic studies in humans proved that the colonic tablets were suitable not only to retard the drug release in upper GIT but also to deliver drugs to colon in slow manner in contrast to IR tablets. In conclusion, development of HPMC K4M-ED S100 compression coated tablets is a good approach to target the FLB in colon and time dependent HPMC K4M compression coated tablets is showed KTM release in colon.