Chapter-6

SUMMARY, CONCLUSION AND RECOMMENDATIONS
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Amongst the avenues investigated so far in a bid to optimize the transportation of these macromolecules transversely through mucosal barricades, the utilization of nanoparticulate system complex looks as challenging as well as potential approach.

Substantial study efforts have been concentrating on development of secure and competent chitosan based colloidal enzyme release systems.

The rationale behind this effort is to assess the opportunity of enzyme treatment for inflammation associated diseases by using serratiopeptidase in biodegradable nanoparticles of chitosan. This bicatalyst has very little biological half life and hence frequent administration (usually three to four times a day) at present makes it a suitable aspirant for controlled release studies.

Serratiopeptidase (SP) is conventionally delivered as an enteric coated product. However, it rapidly degrades under the harsh gastric environment. To protect the enzyme from the harsh gastric challenges, its proteolytic activity, this system may serve as ideal transporter for the buccal or oral management of the enzyme.

In this project work, SP loaded CS nanoparticles were synthesized by ionotropic gelation of CS with TPP anions. Reverse physical cross-joining by electrostatic interface, as an alternative of chemical cross-uniting, has been
made functional to keep away from the potential toxicity of reagents and other disagreeable adverse effects.

The biocatalyst loaded nanoparticle formulations were characterized by outer surface examination, whole protein content, proteolytic activity, FTIR, and enzyme in vitro release studies\textsuperscript{108}.

In vivo studies were carried for assessing Pharmacokinetic, Pharmacodynamic evaluations. The selected enzyme serratiopeptidase was estimated by reported BCA protein method. Standard curve was prepared in PBS (pH7.4) by using BCA working reagent at $\lambda_{\text{max}}$ 562nm.

To achieve the objective, serratiopeptidase loaded Nanoparticles were prepared from CS particulate carriers involving three different Strategies: (a) release from the surface of particles, (b) distribution through the engorged tough matrix and (c) release due to polymer rupture.

Maximum concentration in blood was achieved after 5 hour post administration. Pharmacodynamic studies were conducted by inducing the Carrageenan induced Paw edema classical example for estimating of anti-inflammatory action. The maximum percent inhibition of Paw edema volume was achieved after 5 hour post administration. The marks of in vivo studies were indicative of better formulation design with this transporter system for oral release of enzyme.
A superior conclusion of fundamental action of this novel carrier system will offer foundation for improving the administration of macromolecules. The outcomes acquired in this work are the testimonials for the positive role of CS nanoparticles as a modus operandi that provided stability of serratiopeptidase enzyme, achieving release of active enzyme both \textit{in vitro} as well as \textit{in vivo}. More \textit{in vivo} studies on toxicological evidences are to be carried out.