Chapter III

Aim and objective
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Chitosan is very safe and LD$_{50}$ of chitosan in laboratory mice is 16gm/kg body weight, which is similar to sugar or salt (Arai 1968). In our body, it breaks down slowly to amino sugars which are absorbed by the human body (Nicol 1991). From the literature review it was observed that, though chitosan is used as a polymer in sustained release drug delivery system, sometimes combination of polymer is more effective in developing a drug delivery system than single polymer. As chitosan is a cationic polymer with free amino groups, it can be combined with negatively charged polysaccharide like gum odina. Previously gum odina was used as a tablet binder and a release modifier in the sustained release matrix tablet. However, there is no report available in the literature on the development of microparticulate system using chitosan and gum odina. Glutaraldehyde was used as a crosslinking agent in the preparation of microspheres. Diclofenac sodium is a non-steroidal anti-inflammatory drug with a shorter biological half-life of 1.2–2 h. Its short biological half-life makes it a suitable candidate for the development of sustained release drug delivery system.

**The major objectives of this study are as follows:-**

i) To formulate different formulations of Diclofenac sodium by altering the ratio of chitosan and gum odina and the amount of cross-linking agent for controlled release of the drug.

ii) To characterize the formulation based on their analytical parameters.

   a) Determination of the surface morphology of the formulations by scanning electron microscopic (SEM) analysis.
   b) Measurement of the particle size of all the formulations.
   c) Differential scanning calorimetric (DSC) study.
   d) Fourier transform infrared (FTIR) spectral analysis.
e) To estimate the drug entrapment efficiency of all the formulations.

f) To determine the \textit{in-vitro} drug release characteristics of all the formulations.

g) To study the mechanism and drug release kinetics of all the formulations.

h) \textit{In vivo} study of the prepared formulation and determination of pharmacokinetic parameters.
References
