OBJECTIVES OF THE PRESENT STUDY

3.1. Aim of work

In the context of drug delivery applications, mucoadhesives are used to enhance the overall efficacy of drug delivery. Generally, the mucoadhesive materials employed in drug delivery are polymeric macromolecules of synthetic or natural origin. To avoid the adverse effects such as irritation, non sensitizing and non photosensitizing by using few synthetic mucoadhesive polymers (cellulose derivatives) in various pharmaceutical dosage forms, the proposed study was planned to extract the natural mucoadhesive material from the dried seeds of plants such as *Caesalpinia pulcherrima* and *Leucaena leucocephala*. Then the extracted material is characterized for its mucoadhesive property with a comparative study to the same characterized synthetic or semi synthetic polymers such as Hydroxy propyl cellulose and Sodium alginate. The *In vitro, In vivo* evaluation and the possible physical parameters for the extracted material from the plant seeds are going to be determined.

Theophylline and Salbutamol sulphate are chosen as model drug for the proposed study. The regular evaluation shall conduct on the formulated tablets followed by addition of mucoadhesive characterization. Mucoadhesive capacity of materials can be accessed by analyzing the parameters which will provide the degree of adhesion and the possible methods shall study in our laboratory. These studies may open up new links to identify the exploited mucoadhesive for the therapeutic aspects such as, in the formulation of tablets with various drugs in various dosage forms using these natural mucoadhesive materials to minimize the side effects.
3.2. Plan of work

The present work shall be carried out for development of drug delivery system for Theophylline and Salbutamol sulphate using natural mucoadhesive material from seeds of *Caesalpinia pulcherrima* and *Leucaena leucocephala*.

This work will be carried out in four phases.

3.2.1. Phase I

1. Collection of seeds and plant authentication by Botanical survey of India.
2. Extraction of natural mucoadhesive material from the seeds of *Caesalpinia pulcherrima* and *Leucaena leucocephala*.
3. Identification and purity tests for the Natural mucoadhesive materials.

3.2.2. Phase II

1. Analysis of physicochemical parameters of extracted materials.
   a. pH
   b. Swelling studies at different pH
   c. Melting point
   d. Viscosity at different temperature
   e. FTIR Spectrum
   f. DSC
   g. $^{13}$C & $^1$H NMR analysis

2. Comparative study of mucoadhesive character of extracted natural materials with the HPC and Sodium alginate.
   The different mucoadhesive characterization methods shall consist of
   a. Physical evaluation methods
      i. Shear stress measurement.
      ii. Wilhelmy’s method.
      iii. Falling sphere method.
      iv. Detachment force measurement.
   b. *In vivo* evaluation method
      i. X-ray studies of mucoadhesive tablets using albino rabbits.
3.2.3. Phase III

1. Construction of calibration curve of Theophylline and Salbutamol sulphate.

2. Preformulation studies
   a. Interaction studies of drug and extracted natural mucoadhesive material using infrared and DSC spectrums.
   b. Evaluation of physical characteristics of blend of Theophylline and Salbutamol sulphate.
      i. Angle of repose.
      ii. Bulk density.
      iii. True density.
      iv. Carr’s index.
      v. Hauser’s ratio.

3. Formulation and evaluation of Theophylline and Salbutamol sulphate oral mucoadhesive tablets
   i. Thickness test
   ii. Hardness test
   iii. Friability test
   iv. Weight variation test
   v. Drug content uniformity
   vi. Surface pH determination
   vii. Water absorption studies
   viii. Mucoadhesion strength studies

4. *In vitro* dissolution studies.

3.2.4. Phase IV

1. *In vivo* drug release study using animal model for the best formulations
   i. *In vitro-In vivo* correlation study
   ii. Results based on statistical significance.