Chapter 2

Research Envisaged and Plan of Work
2. RESEARCH ENVISAGED

In the present work it is proposed to prepare and evaluate buccoadhesive formulation of Diltiazem using modified acrylate aimed at reducing drawbacks of conventional formulations. The main benefits envisaged from above studies are:

- Improved oral bioavailability
- Avoidance of first pass metabolism

2.1 Objectives of the work

- Synthesis of acrylate based mucoadhesive polymers and their characterization.
- Designing, characterization and optimization of the formulation.
- Stability studies.
- *In-vivo* evaluation of optimized formulation

**Hypothesis:** Drugs having inherent drawbacks related to poor bioavailability due to first pass metabolism can be effectively delivered by buccal route as a buccoadhesive formulation to improve its bioavailability to considerable extent.

Diltiazem was selected as model drug for investigation because of its properties like high first pass metabolism, half-life of 4.5 hrs, optimum partition coefficient (158) and molecular weight (450.98) (Singh B and Ahuja N *et al*, 2004). Mucosal drug delivery, a promising area for continued research is selected, with the aim of systemic delivery of Diltiazem as well as a feasible and attractive alternative for non-invasive delivery.
2.2 Plan of Work

- Literature survey (Journals, Patents, books & websites)
- Drug & Dosage form selection
- Procurement of Drug and Excipients
  - Analytical method development & validation
  - Polymer synthesis and characterization
  - Drug authentication
  - Excipient compatibility studies
- Preformulation
- Formulation development
  - Buccal Tablet
  - Buccal Patch
    - Design of experiments
    - Swelling index
    - Content uniformity
    - Ex-vivo buccoadhesive strengths
    - *In-vitro* drug release
    - Optimization
- Evaluation
- Stability studies
- *In-vivo* studies