CHAPTER 3
THEORETICAL ANALYSIS

3.1 AIM AND OBJECTIVES

3.1.1 Aim

The majority of the traditional oral drug delivery systems have few impediments which are mainly associated to gastric residence of dosage form. This can be overcome by formulating GRDDS. Repaglinide is an oral hypoglycemic agent belonging to meglitinide class, which requires frequent dosing before every meal due to short half-life (1 h) and thereby imposing side effects such as skeletal muscles pain, headache, gastrointestinal disturbances such as nausea, vomiting and anorexia. Short lasting action, fast clearance and absorption window in upper GIT (stomach), makes repaglinide, as a suitable candidate for developing gastroretentive dosage forms.

The present study intended to develop novel drug delivery systems of repaglinide such as floating and mucoadhesive drug delivery system.

3.1.2 Objectives

- Extraction of okra gum from fresh fruits of *Abelmoschus esculentus* (L.) Moench.
- To conduct experimental studies on okra gum (OG).
- Compatibility study between drug and polymers.
- Preformulation studies.
- To study the effect of independent variables on selected dependent variables by response surface methodology, in designing of floating drug delivery system.
- Preparation of optimized formulation for validation of experimental design, followed by *in vitro* evaluations.
- Evaluation of okra gum for its mucoadhesion potential.
- Synthesis of thiolated okra gum (TOG).
- To evaluate mucoadhesion potential of thiolated okra gum.
- Formulation and *in vitro* evaluation of mucoadhesive tablets of Repaglinide.
- Comparison of dissolution profiles by calculating difference factor ($f_1$) and similarity factor ($f_2$), considering paddle method as reference and modified method as test.
Identification of best formulations.
To investigate the gastric retention time of best formulations by X-ray radiographic studies using animal model.
To determine the bioavailability of drug by pharmacokinetic studies using rabbit as animal model.
To conduct stability studies for best formulations.

3.2 PLAN OF WORK

In order to achieve the above referral objectives, the present study “Development of novel drug delivery systems for repaglinide, an anti-diabetic drug” was designed to carry out in following steps: