CHAPTER - I

INTRODUCTION
AND
OBJECTIVES
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Controlled drug delivery is a topic of current interest in pharmaceutical technology. In recent years considerable attention has been focused on the development of new drug delivery systems known as controlled release drug delivery systems. Such interest is based largely on the fact that the controlled release products have established and retained a place in the market based on their uniqueness and their clinical advantages in the practices of medicine. Controlled release drug delivery systems are those formulations designed to release an active ingredient at rates, which differ significantly from their corresponding conventional dosage forms. The controlled release drug delivery systems are aimed at controlling the rate of drug delivery, sustaining the duration of therapeutic activity and/or targeting the delivery of the drug to a tissue. Drug release from these systems should be at a desired rate, predictable and reproducible. Polymers which are used as release retarding materials in the design of controlled release dosage forms play a vital role in controlling the delivery of drug from these dosage forms.

In this study the dissolution rate of model poorly water soluble drug, prednisolone, was enhanced by the solid dispersion technique and such a dispersion of prednisolone was employed in the formulation of matrix tablets. This is a novel approach in the design of sustained release formulations of poorly soluble drugs. At the same time, a water soluble drug was also made into controlled release tablets employing wet granulation technique.
Hence, in this work, an attempt was made to develop sustained releasematrix tablets of prednisolone by direct compression method using newly developed tamarind kernel gum and hydrophilic matrix materials called hydroxypropyl methylcellulose and Sodium carboxy methyl cellulose. Additionally attempts were made to optimize the matrix tablet formulation to provide a 90% to 100% release at the end of the 12th hour. In the case of diclofenac sodium, wet granulation technique is employed for formulation of controlled release tablets. The general and specific objectives are as mentioned below:

**General objective**

It is to investigate the use of solid dispersion technique in enhancing the solubility and dissolution rate of the poorly water soluble drug, prednisolone, and to study the performance using newly developed tamarind kernel gum and hydrophilic matrix materials called hydroxypropyl methylcellulose and Sodium carboxy methyl cellulose in the development of a controlled release matrix tablet employing the solid dispersion of the drug that could give 90 to 100% release in a 12 hour period. In the case of diclofenac sodium, wet granulation technique is employed for formulation of controlled release tablets. The specific objectives of the investigation are as follows:

1. Preparation and evaluation of tamarind kernel gum.
2. Preparation of co-precipitate, co-ground and physical mixtures of prednisolone.
3. Estimation of drug content of solid dispersions of prednisolone.

4. Determining the solubility of prednisolone in HCl buffer (pH 1.2) and phosphate buffer (pH 6.8) and in solutions containing different concentrations of the carrier.

5. Studying the dissolution of prednisolone in pure form and from various mixtures prepared, in both HCl buffer (pH 1.2) and phosphate buffer (pH 6.8).

6. Preparation of prednisolone matrix tablets by direct compression method.

7. Evaluation of the prepared tablet and design of sustained release tablet that gives 90 to 100% release in a 12-hour period.

8. To evaluate the drug release kinetics and mechanism of prednisolone matrix tablets prepared.

9. To develop controlled release tablets of (i) Prednisolone and (ii) Diclofenac sodium for twice-a-day (12 hrs) administration.

10. To evaluate the stability of drug release characteristics of selected promising formulations.

11. *In-vivo* evaluation of selected formulations developed in rabbits.

Both *in-vitro* and *in-vivo* has been carried out to fulfill the objectives of the investigation and the studies carried out and the results obtained are described in the next coming chapters.