CHAPTER 3

RESEARCH ENVISAGED

AND PLAN OF WORK
3. Aim, Objectives and Plan of Work

3.1 Aim
The aim of this work is, to develop extended release formulations of antiviral drugs namely Zidovudine and Nevirapine using a controlled release polymer.

3.2 Objectives
The objective of this dissertation is to develop extended release (ER) formulation for antiviral drugs Zidovudine and Nevirapine, 300 mg and 400 mg respectively using hydroxypropyl methyl cellulose as a main polymer. Literature study reveals that drugs from the class of antiviral drugs are not only required to be given in larger doses but also more frequently, owing to their short half-life. Such drugs will obviously be advantageous if they are to be formulated as extended release as this will reduce the dosing frequency, improve the patient compliance and also reduce the dose dependent side effects. The objectives of the studies are given below.

1. To develop stable extended release (ER) matrix tablet for Zidovudine 300 mg and compare in vivo release profile with innovator’s immediate release tablet.

2. To develop stable extended release (ER) matrix tablet for Nevirapine 400 mg and to match the dissolution profile of the innovator formulation.

3. To screen the important Critical Material Attributes (CMA) of Active pharmaceutical ingredient (API), various excipients and Critical Process Parameters (CPP) of the formulation process on the dissolution profile of Nevirapine using QbD approach for Nevirapine.

4. To achieve process optimization and scale up studies of ER formulations for both drugs i.e. Zidovudine and Nevirapine.
3.3 Plan of Work

This work was divided as shown below.

**Part I: Preparation, optimization and scale up of extended release (ER) matrix tablets of Zidovudine 300 mg.**

2. Formulation trials, Design trials.
3. Complete characterization of formulation like hardness testing, assay, dissolution.
4. *In vitro* studies of optimized formulation with IR tablet.
5. Stability study of final formulation.
7. Scale up studies.

**Part II: Preparation, optimization and scale up of extended release (ER) matrix tablets of Nevirapine 400 mg.**

2. Innovator product characterization.
3. Formulation trials based on QbD approach i.e. considering effect of critical material attributes and critical process parameters on critical quality attributes (CQAs), Design trials.
4. Complete characterization of formulation like hardness testing, assay, dissolution.
5. Stability study of final formulation.
7. Scale up studies.