CHAPTER 3

SCOPE AND OBJECTIVES OF THE STUDY

The need for delivering drugs to patients efficiently with minimum side effects has prompted pharmaceutical industries to be engaged in development of new drug delivery systems. Paediatric and geriatric patients find it difficult to swallow solid dosage forms like tablets. Mouth dissolving tablet that dissolve or disintegrate rapidly in oral cavity result in solution, is an ultimate remedy for this problem. In addition they give pleasing mouth feeling. ODT has advantages such as patient compliance, quick onset of action, improved bioavailability, etc. Therefore, mouth dissolving tablets are attractive alternative to liquid and conventional tablet dosage forms. In recent past, several manufacturing technologies such as sublimation technique, spray drying technique… etc. are employed to overcome the limitations of conventional tablet dosage forms. Once the mouth dissolving tablets are prepared they are required to be evaluated for various parameters so as to have long term stability and better therapeutic efficacy.

3.1 OBJECTIVES

The main objectives of the present study are:

- To design and develop orodispersible tablets, chewable tablets and bilayer tablets for the widely used anti-allergic drug, Loratadine and phenylephrine using suitable super disintegrants and special tablet excipients.
- To carry out pre-formulation studies on the selected drug and excipients.
- To carry out physico-chemical evaluation tests for the granules of the formulations developed such as bulk density, taped density, compressibility index, Hausner's ratio and angle of repose.

- To carry out physico-chemical evaluation tests for the formulations developed such as thickness, hardness, weight variation test, dispersion test, disintegration test and drug content uniformity.
- To study the *in vitro* drug release studies using suitable dissolution apparatus.
- To perform stability studies for the selected best formulations as per ICH Guidelines to be performed.

3.2 PLAN OF WORK

3.2.1 Oral dispersible tablets

1 Preformulation studies

DSC studies to study the possible chemical interaction between the excipient and drug.

Construction of standard graph in 0.1M phosphate buffer pH 2.

2 Preparation of oral dispersible tablets of Loratadine containing super disintegrants by direct compression method.

3. Evaluation of oral dispersible tablets
    - Friability
    - Hardness
    - Weight variation
    - Disintegration time
    - Water absorption ratio
    - Wetting time
    - Drug content uniformity
4. Evaluation of *in vitro* release characteristics using USP dissolution apparatus 1 (Basket).

5. Intermediate and accelerated stability studies of optimized formulation as per ICH Guidelines to be performed.

3.2.2. Chewable tablets

1 Preformulation studies

DSC studies to study the possible chemical interaction between the excipient and drug.

2. Preparation of chewable tablets of Loratadine containing different excipients by wet granulation method.

3. Evaluation of blend

- Angle of repose
- Bulk density
- Tapped density
- Compressibility index
- Hausner's ratio
- Loss on drying

4. Evaluation of chewable tablets

- Weight variation
- Hardness
- Friability
- Thickness
- Drug content uniformity

5. Evaluation of *in vitro* release characteristics using USP dissolution Apparatus 2 (paddle).

6. Intermediate and accelerated stability studies of optimized formulation as per ICH Guidelines to be performed.

3.2.3. BILAYER TABLETS

1 Preformulation studies

DSC studies to study the possible chemical interaction between the excipient and drug.

2. Preparation of immediate release layer of Loratadine

3. Evaluation of blend

- Bulk density
- Tapped density
- Carr's compressibility index
- Hausner’s ratio
- Particle size distribution

4. Evaluation of tablets

- Hardness
- Friability
- Thickness

5. Preparation of phenylephrine HCl sustained release layer

6. Evaluation of blend

- Bulk density
- Tapped density
- Carr's compressibility index
- Hausner’s ratio
- Particle size distribution

7. Evaluation of tablets

- Hardness
- Friability
- Thickness

8. Evaluation of *in vitro* release characteristics using USP dissolution apparatus 2 (paddle).

9. Intermediate and accelerated stability studies of optimized formulation as per ICH Guidelines to be performed.