3. OBJECTIVE OF RESEARCH WORK

The present invention relates to formulation and development of bi-layer solid dosage forms having an immediate release layer and a slow release layer with each layer containing Losartan potassium as an active ingredient.

The solid dosage form of the present invention features a balance between immediate release and sustained release of Losartan which provides a significantly more uniform, efficient delivery of Losartan than oral formulations of Losartan now available in the market. This dosage form may be used for the same indications as the Losartan tablets now in clinical use. However, it is especially useful where it is desirable to maintain a sustained, uniform dose of Losartan potassium for twelve to twenty four hours with the administration of only one dose as well as with an immediate effect.

In particular the solid dosage form of the present invention may be in the form of a compressed bi-layer tablet having at least one layer containing Losartan potassium formulated as immediate release and another layer containing Losartan potassium formulated for sustained release.

3.1 Plan of Research Work

- Preformulation study
- Optimization of formulation variables during the production of batches.
  - Formulation variables : Polymer concentration/ratio.
    Drug concentration.
    Amount of organic solvent.
  - Process variable : Speed of Stirring
• Preparation of optimized microsphere formulation batches using double emulsion solvent evaporation and emulsion solvent evaporation techniques.

• Characterization of Losartan potassium loaded Eudragit microspheres.
  - % Yield Value.
  - Drug Loading and Encapsulation efficiency.
  - Micromeritic Properties of Microspheres.
  - Particle size distribution analysis.
  - Scanning electron microscope analysis.
  - Solid state interaction studies.
    - a) FT-IR spectroscopy.
    - b) Proton NMR spectroscopy.
  - Thermal analysis of Drug crystallinity (DSC).
  - Crystallographic characterization using powder-XRD.
  - In vitro drug release study in 0.1M HCl & Phosphate buffer saline pH 7.4.

• Preparation of Bi-layer tablet having an immediate release layer and a slow release layer with each layer containing Losartan potassium as an active ingredient

• Evaluation of tablet