3.1 Objective

Diclofenac sodium is non-steroidal anti-inflammatory drug (NSAID); it is used in pain management associated with cancer, arthritis or acute injury. Thus an extended release formulation of diclofenac sodium is required for patient compliance. Presently, diclofenac sodium (Voveran SR) is available in commercial market and is based on hydrophilic matrix using hypromellose.

3.2 Aim

The aim is to formulate an extended release matrix tablet of diclofenac sodium based on hydrophobic matrix using ethyl cellulose polymer.

To achieve an extended release profile of diclofenac sodium following variables of the formulation will be evaluated:-

1. Effect of increasing hardness on release rate- Optimized formula will be compressed at different hardness to evaluate its effect on drug release.
2. Effect of particle size and viscosity grade of ethyl cellulose- Formulations will be formulated with ethylcellulose using different grades and particle size, i.e. Standard Premium and Fine Particle.
3. Effect of various diluents with their mechanical properties i.e. elasticity or plasticity- Formulations will be prepared by using different diluents like microcrystalline cellulose, lactose, dicalcium phosphate.
4. Effect of increasing binder concentration in formula- Formulation will be prepared by increasing binder concentration.
5. Effect of manufacturing process- Tablets will be prepared with two methods i.e. direct compression and wet granulation.

3.3 Plan of Work

3.3.1 Preformulation studies:

- Determination of saturation solubility of Diclofenac sodium
- Diclofenac sodium Excipient compatibility studies
Determination of absorbance maxima of the Diclofenac sodium

Preparation of calibration curve for the Diclofenac sodium

Solution state stability of Diclofenac sodium over 24 hours

3.3.2 Formulation Development and Evaluation of Matrix tablets:

3.3.2.1 Preparation of formulation with two processes

- Direct compression
- Wet granulation

3.3.2.2 Characterization of the granules prepared by selected manufacturing process

- Bulk density.
- Tapped density.
- Carr’s Index.
- Hausner’s Ratio.
- Angle of Repose.

3.3.3 Compression of batches with round shaped punches.

3.3.4 Evaluation of tablets

- Weight variation test
- Hardness
- Thickness
- Friability
- Dissolution Studies

3.3.5 Optimisation of batches with differential amounts of suitable polymer used in trial batches.
3.3.6 To study the effect of hardness on percentage release of the Diclofenac sodium from the optimised batch made with suitable polymer.

3.3.7 Evaluation of *in vitro* drug release kinetic models.

3.3.8 Comparison of selected batch with commercial product (Voveran SR).