3. AIMS, OBJECTIVES AND PLAN OF WORK

Majority of drug products available in market suffer from solubility problems. Because of poor solubility, good numbers of new molecules are not reaching the market. The solubility can be enhanced by several techniques. One of the prominent approaches to enhance solubility is the complexation with β-cyclodextrin and formation of solid inclusion complex.

Cyclodextrins are employed as complex forming agents thereby enhancing the aqueous solubility of poorly soluble drugs. Thus they improve the bioavailability and stability of drugs, reduce gastrointestinal drug irritation, prevent drug–excipient and drug–drug interactions. To overcome gastrointestinal tract irritant effects caused by many of non-steroidal anti-inflammatory drugs, it becomes necessary to formulate the drug in an appropriate dosage from which can be administered through skin.

3.1 Aims and Objectives

The aims of present study were to enhance solubility of anti-inflammatory drug Meloxicam by inclusion complexation with prepare inclusion complexation with β-cyclodextrin and prepare gels and patches containing complex and to evaluate the formulations.
The objectives of this study were as follows:

1. To procure pure drug and authenticate by analytical techniques.
2. To formulate and perform characterization studies on the inclusion complexation of Meloxicam-β-cyclodextrin complex.
3. To formulate and evaluate gel and patch containing Meloxicam-β-cyclodextrin complex.
4. To perform stability studies on gel and patch containing drug and its complex with β-cyclodextrin.
5. To perform stability studies on gel and patch containing Meloxicam and Meloxicam complex.
6. To study the skin irritation index and anti-inflammatory studies on optimized formulations of gels and patches.

3.2 Plan of work

1. Procurement of pure drug
2. Preformulation studies for the Meloxicam including:
   - Determination of melting point
   - Determination of \( \lambda \) max
   - Determination of Solubility
   - Determination of pH
   - Determination of Partition-coefficient
   - FT-IR studies
   - DSC analysis
3. Preparation of inclusion complex of Meloxicam-β-cyclodextrin by suitable technique
4. Characterization of Meloxicam-β-cyclodextrin complex
   - Determination of Solubility
   - FT-IR studies
   - DSC analysis
5. Formulation of gels containing drug and its complex
6. Characterization of gels containing drug and its complex
AIMS, OBJECTIVES AND PLAN OF WORK

- Appearance
- Determination of pH
- Studies of rheological properties
- Drug content uniformity
- *In-vitro* drug diffusion studies across cellophane membrane/ goat abdominal skin

7. Formulation of patches containing drug and its complex

8. Characterization of patches containing drug and its complex
   - Physicochemical characteristics of films
   - Drug content uniformity of films
   - *In-vitro* drug diffusion studies across cellophane membrane/ goat abdominal skin

9. Studies of skin irritation index and anti-inflammatory studies of optimized preparations of gels and patches.

Accelerated stability studies on gel and patch according ICH guidelines