Work Plan & Methodology:

1. Literature survey:
   Review of literature related to Drug Profile, excipients profile and Formulation development.

2. Identification, Selection, and characterization of drug and excipients.

3. Preformulation study.
   Compatibility Study drug excipient interaction study is necessary prerequisite to development of dosage form that are stable and good quality.

4. Formulation and Development of Pulsatile drug delivery systems.
   A. Development of formulation by using different polymers and study effect of polymer in pulsatile drug delivery system.
   
   B. Design and Development of pulsatile release system by using various methodologies.
   
   C. Optimization of Formulation.

5. Evaluation of the formulations.
   A. Physical properties
   B. Chemical properties

6. Stability studies of the formulation.
   Accelerated and long term stability study.

7. Result and discussion
Methodology:

Patient suffering from rheumatoid arthritis feel more pain in morning period while patient suffering from osteoarthritis feel less pain in morning than night. Thus in such disease condition, release of some drug is ideal in pulse pattern. In the arthritis pain in the joints is severe in the early morning. So patients using conventional tablet must wake up in the morning and take tablet at mid night due to short biological half life of drug products.

To coincide with the release of these inflammatory cytokines and peak plasma aceclofenac levels, A pulsatile drug delivery system formulations were developed to alleviate the symptoms of morning stiffness in patients with rheumatoid arthritis pulsatile drug delivery system formulations are for oral administration at bed-time, releases aceclofenac after a desired lag time of about 360 minutes which corresponds with peak levels of proinflammatory mediators. For development of pulsatile drug delivery selection of proper methodology impotent so that drug release after appropriate lag time.

There are various methods are available for develop the pulsatile drug delivery but those methods have disadvantages Lack of manufacturing reproducibility and efficacy, Large number of process variables, Multiple formulation steps, Higher cost of production, Need of advanced technology. So press coated /compression coated tablet methodology selected for development of pulsatile drug delivery.

Compression coating can involve direct compression of both the core and the coat, obviating needs for separate coating process and use of coating solutions. The outer tablet of the compression-coated tablet provides the initial dose, rapidly disintegrating in the stomach and the inner layer is formulated with components that are insoluble in gastric media but are released in the intestinal environment. Materials such as hydrophilic cellulose derivates can be used. Compression is easy on laboratory scale. The major drawbacks of the technique are that relatively large amounts of coating materials are needed and it is difficult to position the cores correctly.

Press-coated pulsatile drug delivery systems:

1. Press-coated pulsatile drug delivery systems can be used to protect hygroscopic, light-sensitive, oxygen labile or acid-labile drugs.
2. Press-coated pulsatile drug delivery systems are relatively simple and cheap.
3. These systems can involve direct compression of both the core and the coat.
4. Materials such as hydrophobic, hydrophilic can be used in press-coated pulsatile drug delivery system.
5. Press-coated pulsatile drug delivery systems involve compression which is easy on laboratory scale.
6. Press-coated pulsatile formulations release drug after “lag-time”.
7. Press-coated pulsatile drug delivery formulations can be used to separate incompatible drugs from each other or to achieve sustained release.

**Design and Development of Time controlled pulsatile release system by using press coated/compression coated tablets:**

A. Development of formulation by using different polymers hydrophilic and hydrophobic polymers and study effect of polymers on drug release properties.

B. Design and Development of pulsatile release system by using various press coated tablet methodology. Development of different formulation by using
   1. Delivery systems with rupturable coating layer.
   2. Delivery systems provided with erodible coating layers.