4. Work Plan and Methodology

Work Plan

1. Literature survey
2. Selection and Procurement of drug and excipients.
3. Preformulation study of drug and excipients.
   a. Solubility of drug and excipients
   b. Identifying purity by UV spectroscopy, IR spectrometry
4. To optimize cefotaxime microparticles
   a. Using different solvents and polymers by emulsion solvent evaporation method.
5. Characterization of optimized microparticles by suitable methods
6. In-vitro evaluation of microparticles containing drug
7. Stability testing
   a. Stress testing of the microparticles as per ICH guidelines

Methodology

Review of literature

Documentation requirements, the process approach, outsourced processes were collected from journals, text books, internet, official books, patents and other related articles. Guidelines related to the statutory bodies like FDA (Food and Drug Administration), WHO (World Health Organization), ISO (International Organization for Standardization), ICH (International Conference on Harmonization) etc will be utilized.

Selection and Procurement of drug and excipients

The selection of antibiotic drug cefotaxime and the purity of the same will be determined by IR (Infrared Spectroscopy). Drug and excipients are planned to procure from standard source of right purity to establish the activity of pure individual component.

Preformulation investigation of drug and excipients

The considered drug and excipients will be optimized by preformulation studies to identify the solubility and possible interaction between the drug and excipients.
To optimize cefotaxime microparticles
To select and prepare the drug containing microparticles with the suitable excipients from the optimized one.

Characterization of prepared microparticles by appropriate methods
It is planned to adopt suitable method to characterize the optimized formulation by various methods to assess particle size and surface morphology.

In-vitro evaluation of microparticles containing drug
In-vitro evaluation of the optimized microparticles will be performed. Suitable methods will be utilized to study the formulation.

Stability testing
As per ICH guidelines the optimized formulation will be subjected for stress testing. Samples will be withdrawn at regular intervals to assess the content uniformity and stability.