3. Plan of work

3.1. Objectives

- To develop a polymer based nanoparticulate drug delivery system for Berberine Chloride.
- To develop a platform technology for oral delivery of nanoparticulate drug delivery system.
- To assess the bioavailability and toxicological profile of optimized formulation on rats.

3.2. Detailed Experimental Plan

3.2.1. Solubility Studies

HPLC analytical method development for estimation of BBR

Solubility study in aqueous, different pH solutions and surfactants

3.2.2. Development of Berberine Chloride Nanoparticles (BBR-NP) and Vitamin E TPGS Surface Coated Berberine Chloride Nanoparticles (BBR-SCNP)

Optimization of process variables

Optimization of formulation variables with quality by design (QbD) and preparation of BBR-NP

Preparation BBR-SCNP

3.2.3. Development of Naplet Technology

Preparation of naplets by in-house method

Optimization of binding and disintegrating agents concentration

Sub and enteric coating of naplets

3.2.4. Characterization of Nanoparticles and Naplet

Particle size and polydispersity index

Zeta potential

Entrapment efficiency

Fourier Transform Infra Red (FT-IR)

Differential Scanning Calorimetry (DSC)

Powder X-Ray Diffraction (PXRD)

Transmission Electron Microscopy (TEM)

Scanning Electron Microscopy (SEM)

Disintegration and redispersion of Naplet

Hardness and friability of Naplet

3.2.5. In-vitro Drug Release and Kinetic Study

3.2.6. Stability Studies

3.2.7. Pharmacokinetic Study

HPLC bio-analytical method development for quantification of BBR

Oral single dose animal study

3.2.8. Haemocompatibility Study

3.2.9. Toxicity Studies

Histopathological study

Biochemical estimations