3. Plan of work

3.1. Objectives

Primary Objective

To develop intranasal delivery system for asenapine with improved bioavailability and sustained delivery.

Secondary Objective

- To prepare and characterized asenapine loaded nanostructure lipid carriers (ANLC).
- To prepare and characterized glycol chitosan coated asenapine loaded nanostructure lipid carriers (GC-ANLC).
- To perform pharmacokinetic study to access bioavailability.
- To evaluate both uncoated and coated nanostructure lipid carriers in suitable animal model for antipsychotic potential and side effect.
- To assess the toxicological profile of optimized formulation on rats.

3.2. Detailed experimental plan

3.2.1. HPLC analytical method development

3.2.2. Development of asenapine loaded nanostructured lipid carriers

Quality target product profile

Critical material attributes and process parameter

Formulation development by quality by design

3.2.3. Preparation of Glycol chitosan coated nanostructured lipid carriers

3.2.4. Characterization and optimization of ANLC and GC-ANLC

Particle size, polydispersity index and zeta potential

Entrapment efficiency

3.2.5. *In-vitro* drug release study

3.2.6. Solid state characterization

Fourier transform infrared spectroscopy

Differential scanning calorimetry

X-Ray Diffraction

3.2.7. Surface characterization

Transmission electron microscopy

Atomic force microscopy

3.2.8. Stability Studies

3.2.9. *In-vitro* cell viability study

3.2.10. *In-vivo* pharmacokinetic study

3.2.11. Animal behavioural studies

Induced locomotor activity test

Paw test

Catalepsy test

3.2.12. Toxicity studies

Nasal toxicity study

Embryo fetal toxicity study