WORK PLAN&METHODOLOGY

The proposed plan of work is summarized below in phased manner. Research work will be undertaken in a period of 2 years in following phases:

Phase I (0-2 months): Review of Literature

Phase II (3-6 months): Procurement of chemicals and selection/optimization of suitable HPLC and/or LC-MS/MS method

Reference (or analytical) standard will be procured. Based on literature review and projected studies, other required materials will be arranged.

Phase III (7-12 months)

Development of bioanalytical method:

Bioanalytical method development leading to method validation is proposed to involve certain essential stability considerations also; besides optimization of selectivity, sensitivity and accuracy. Stability studies involve investigations of drug stability in bio matrices e.g. blood, plasma, tissue homogenate etc. and access drug stability in storage solution/s. The following stability aspects are proposed to be tested/ documented.

- Bench top stability
- In-Injector stability
- Freeze-thaw cycle and long term stability

These studies will be conducted by experiment design created with reference to validation guidance issued by US-FDA regulatory agency. {FDA (2001)}.