4. WORK PLAN & METHODOLOGY

1. Review of literature:
   Review of literature will be done on spherical crystallization, drugs with poor flow properties, oral solid dosage form, role of polymers and their properties.

2. Selection of drug and solvent selection:
   Drug with poor micromeritic properties will be selected and solubility study in different organic solvents will be carried out. The selection of good solvent, poor solvent and bridging liquid will be done based on results obtained in solubility study.

3. Preliminary trials:
   a. Spherical crystals will be developed with and without polymer addition.
   b. Variable parameters will be checked to optimize the spherical crystals. Such as
      - Speed of agitation (rpm)
      - Polymers & its concentration
      - Amount and type of polymer
      - Mode of addition of bridging liquid
   c. Finalization of every steps and amount of materials will be done.

4. Evaluation of optimized spherical crystals and dosage form will be done by various techniques:
   a. Spherical crystals:
      1. Drug Loading Efficiency and % Yield of spherical Crystals,
      2. Microscopic Determination,
      3. Flow Parameters,
      4. Sphericity Determination,
      5. Packability and compressibility will be assessed by analysis of the tapping process.
      6. Crushing Strength of agglomerates will be determined.
      7. DSC, FT-IR, XRD will be performed.
   b. Dosage form:
      1. Friability,
      2. in-vitro disintegration and dissolution study.
      3. Tablet elastic recovery test and Tablet tensile strength.

5. Stability data collection of developed dosage form will be done as per ICH guidance.

6. Complete comparison with formulated dosage form with the innovator.