Work Plan and Methodology

The research shall be carried out as follows:

A. **Literature reviews** carried out from published research work, books, e-sources, patents etc., Acquire polymers and drugs from appropriate sources.

B. **Preliminary screening of formulation:**

   The formulations (tablets) will be prepared by utilizing HPMC K15M, K4M, PEO 303, PEO N60-K and Kollidon SR at different polymer levels. Microspheres loaded with Alfuzosin hydrochloride will be prepared by Emulsion solvent evaporation method.

C. **Preparation of modified release formulations (tablets and microspheres)** will be prepared by direct compression and microspheres will be formulated using different polymers Eudragit S 100, Kollidone SR, cellulose acetate, Acrycoat S 100, Methocel K4M, Methocel K15M, Methocel K100M, and PEO.

D. **Optimization** of polymer/other excipients concentration for tablets and microspheres using box-behnken design\[^{[28-30]}\].

E. **Evaluation of the modified release formulations like tablets and microspheres:**

   i) **Physico-chemical Properties of modified release Tablets:**

      The thickness, hardness, weight variations, and content uniformity of fabricated tablets will be determined by procedure stated in the US pharmacopoeia.

      i) **In Vitro Drug Release Studies (Tablets/Microspheres):**

         Dissolution study shall be carried out under sink condition using USP 27 apparatus 2 (paddle) for tablets. The drug release studies shall be carried out using six basket dissolution apparatus USP type II for microspheres.

      iii) **Determination of drug loading and encapsulation efficiency(microspheres):**

         The Alfuzosin hydrochloride content in the microspheres will be determined by pulverizing the Alfuzosin hydrochloride loaded microspheres.

   iv) **Surface Topography (SEM):**
The surface morphology, shape and to confirm the hollow nature, microspheres shall be analyzed by scanning electron microscopy for selected batches.

The promising formulations shall be carried out for stability study for a period of 3 months as per ICH guidelines.