Work Plan and Methodology

The investigation consists essentially of the following steps:

A. Literature reviews and acquire samples

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

B. Preformulation studies

Preformulation studies like solubility in different solvents, drug-excipient compatibility studies using DSC/FTIR.

C. Preparation of gastroretentive formulations (Tablets/microspheres)

Preparation of gastroretentive tablets by direct compression and gastroretentive microspheres containing different mucoadhesive polymers by emulsion solvent evaporation method using different polymers.

D. Optimization of gastroretentive formulations (Tablet/microspheres)

Formulation shall be optimized for polymer/ other excipients concentration and other parameters like for tablet, in vitro drug release, in vitro mucoadhesion and total floating time and for microspheres solvent ratio, stirring speed, in vitro drug release etc using $3^2$ factorial design.

E. Evaluation of the gastroretentive formulations (Tablets/microspheres) by following methods,

i) Physico-chemical Properties of Floating Tablets

The thickness, hardness, weight variations, and content uniformity of fabricated tablets by procedure stated in the US pharmacopoeia (USP, 2006), density Measurements using their volumes and masses.

ii) In Vitro Buoyancy Studies (Tablets/Microspheres)\textsuperscript{29}

In vitro buoyancy studies by measuring buoyancy lag time and total floating time.

iii) In Vitro Mucoadhesion (Tablets/Microspheres)\textsuperscript{30}
In vitro mucoadhesion by using a texture analyzer.

iv) Water Uptake Study (Tablets/Microspheres)

Water uptake study by measuring swelling index.

v) In Vitro Drug Release Studies (Tablets/Microspheres)

The release of drug using USP XXII apparatus and performs kinetic analysis of the release data.

vi) Loading Efficiency and Encapsulation Efficiency (Microspheres)

Loading efficiency and encapsulation efficiency by appropriate formula.

vii) Morphology (Microspheres)

The surface morphology of the microsphere by scanning electron microscope particle size analysis.

F. Stability studies

The promising formulation is tested for stability study for a period of 3 months as per ICH guidelines.