

*Chapter 2*  
*Aims and Objectives*

---

**AIMS AND OBJECTIVES****Part A: Segregated drug delivery of two incompatible drugs: Rifampicin (RIF) and Isoniazid (INH).****Objectives:**

- To prepare and evaluate enteric coated SR formulations of INH.
- To study interaction of RIF with developed enterosoluble INH in fixed dose combination.

**Specific aims:**

- To employ systemic quality by design approach for formulation development.
- To prepare and optimize tablet and pellet formulations of INH.
- Formulation and/or process parameter optimization using design of experiments wherever applicable.
- To study interaction of RIF and INH in FDC of prepared novel formulation.
- Short term stability studies.

**Part B: Acid labile drug that require to be release in intestine: Lansoprazole (LSP).****Objectives:**

Preparation and evaluation of enterosoluble microparticles of LSP using spray drying technique.

**Specific Aims:**

- To prepare enterosoluble dispersion in form of microparticles by spray drying technique from preferably aqueous solutions.
- To prepare and evaluate enterosoluble microparticles with various enteric polymers, combination with enteric polymers and selection of suitable polymer/polymeric combinations from same.
- To optimize spray drying process to get desired product attributes.
- To evaluate entrapment efficiency, *in vitro* gastric resistance and other physicochemical properties of prepared enteric microparticles.
- Short term stability studies.

**Part C: Prevent precipitation of weakly basic drug at intestinal pH:  
Dipyridamole (DPL).**

**Objectives:**

- To prepare and evaluate solid dispersion with polymers and complex formation with fumaric acid for solubility enhancement and inhibiting precipitation of DPL upon acid to neutral pH transition.

**Specific aims:**

- Selection of polymer and its concentration for solid dispersion.
- Preparation of complex formation with fumaric acid.
- Solubility studies.
- Dissolution studies of prepared solid dispersion and complex formation.
- *In vitro* cell line studies.
- Short term stability studies.