4.1 Rationale

Treatment of hypertension using Carvedilol, Felodipine, Tadalafil and Telmisartan have shown drawback of poor oral bioavailability due to poor or low aqueous solubility and extensive first pass metabolism. These drugs also show slow onset of action and problem of swallowing (dysphasia) in elderly patient on their oral delivery with other solid dosage forms.

4.2 Hypothesis of the study

It was hypothesized that fast dissolving oral films containing drug in solid dispersion (SDP) form may improve the oral bioavailability by rapid dissolution of drug, avoiding first pass metabolism and thus may provide faster onset of action with avoidance of problem of dysphasia.

4.3 Aims and Objectives

The present research work was aimed for the development and evaluation of fast dissolving oral film containing solid dispersion of some poorly water soluble drugs by the application of quality by design (QbD) for the improvement of their oral bioavailability, avoidance of first pass metabolism, providing faster onset of action and avoidance of problem of dysphasia.

4.4 Expected Outcome

Poor aqueous solubility of drug candidates often leads to poor absorption and bioavailability from the GIT, which presents the formulation scientists with considerable challenges when trying to deliver these drug molecules via oral route. The active drug must first dissolve in the GI fluids before it can diffuse through the GIT membranes and then reach systemic circulation for drug absorption. Designing of fast dissolving oral films (FDFs) containing SDP of these poorly soluble drugs may enhance the dissolution (solubility), absorption, bioavailability by avoiding first pass effect and thus provide faster onset of action. The FDFs are seemed to be an ideal dosage form for use in especially in geriatric patients by overcoming the problem of dysphasia. FDFs may provide combined advantages of high stability of a solid dosage form and the better applicability of a liquid dosage form.