CHAPTER-3

Aim, objectives and rationale of work

3.1 Objectives and rationale of work

➢ To develop and validate analytical methods for simultaneous estimation of anti-hypertensive drugs in pharmaceutical dosage form.

➢ There are numbers of newer antihypertensive drugs and their formulations are approved by FDA which is either new molecule or partial modification of existing molecule.

➢ These newer drugs and their combinations are not official in any pharmacopeias and it takes more time to include these drugs and their combinations, in pharmacopoeia due to unavailability of proper analytical methods for their estimation.

➢ There is continuous and longer use of these drugs individually newer side effects, toxicity, resistances are observed.

➢ Development & validation of methods as per ICH Q2 (R1) for newer combinations help to detect drug substances present in diluent and excipients.

➢ Also as per latest DCGI guidelines assay studies for newer drugs combinations are mandatory for launching of drugs in market and for proper patient use.

➢ So present investigation was undertaken with a view to develop and validate new analytical method for simultaneous estimation of Olmesartan medoxomil & Indapamide, Olmesartan medoxomil & Chlorthalidone, Rosuvastatin calcium & Hydrochlorothiazide, Nebivolol HCl & Chlorthalidone, Metoprolol succinate and Chlorthalidone.

➢ Newly developed methods & validated method as per ICH Q2 (R1) may be applied for routine analysis of drug samples in analytical development laboratories and quality control laboratories (USFDA, MHRA, EU, Brazil, and Canada, WHO approved).
3.2 Aim of work

- To develop RP-HPLC methods for simultaneous estimation of Olmesartan medoxomil and Indapamide, Olmesartan medoxomil and Chlorthalidone, Nebivolol HCl and Chlorthalidone, Rosuvastatin calcium and Hydrochlorthiazide, Metoprolol succinate and Chlorthalidone in combination drug products.

- To develop UV or HPTLC methods (wherever UV method is not feasible) for simultaneous estimation of Olmesartan medoxomil and Indapamide, Olmesartan medoxomil and Chlorthalidone, Nebivolol HCl and Chlorthalidone, Rosuvastatin calcium and Hydrochlorthiazide, Metoprolol succinate and Chlorthalidone in combination drug products.

- All developed methods to be validated for specificity, linearity, accuracy, repeatability (precision), and ruggedness, limit of detection and limit of quantification, robustness and system suitability as per ICH Q(2) R1 guidelines.

- To perform statistical comparison of developed methods.