4 AIM AND OBJECTIVES OF THE STUDY

Hypertension is one of the most common and powerful risk factors for cardiovascular diseases. Blood pressure control is prerequisite for the management of cardiovascular diseases and complications. More than one medication is required for effective control of blood pressure of cardiovascular patients. ALI (alkiren hemifumarate) is the first and only representative of a new class of non peptide, low molecular weight; orally active transition state rennin inhibitor. ALI shows effective control of blood pressure and cardiovascular diseases when combined with AMLO (amlodipine besilate), HCT (hydrochlorothiazide) and VAL (valsartan). Literature survey reveals various analytical methods for the estimation of ALI alone and with other drugs in combinations like AMLO, HCT and VAL by UV spectroscopy, HPLC and electrophoresis. There was no reported HPTLC method for the estimation of ALI alone or in combination with other drugs. Still there was a scope for developing more sensitive methods for the determination of ALI in combination with other drugs in their tablet dosage form which can cover up the lacuna of some existing methods. Therefore, aim of the present work was to develop and validate some simpler, sensitive, precise, accurate and cost effective UV spectroscopic, RP-HPLC and HPTLC method compared to existing methods for the determination of ALI, AMLO, VAL and HCT in various tablet formulation.

The objective of the present study was to develop and validate newer analytical methods as per ICH guidelines [24] as follows:

1. To develop and validate a simultaneous equation method for the quantitative determination of aliskiren hemifumarate and hydrochlorothiazide in tablets.
2. To develop and validate an absorbance ratio (Q analysis) method for the simultaneous determination of aliskiren hemifumarate and hydrochlorothiazide in tablets.
3. To develop and validate a first-derivative (zero crossing) spectroscopic method for the simultaneous determination of aliskiren hemifumarate and hydrochlorothiazide in tablets.
4. To develop and validate a highly sensitive RP-HPLC method for the simultaneous analysis of aliskiren hemifumarate and hydrochlorothiazide in tablet formulation.
5. To develop and validate a simultaneous equation method for the determination of aliskiren hemifumarate and valsartan in combined tablet dosage form.

6. To develop and validate an absorbance ratio (Q analysis) method for the simultaneous determination of aliskiren hemifumarate and valsartan in tablets.

7. To develop and validate a first-derivative (zero crossing) spectroscopic method for the simultaneous estimation of aliskiren hemifumarate and valsartan in tablets.

8. To develop and validate a RP-HPLC method for the simultaneous determination of aliskiren hemifumarate and valsartan in tablets.

9. To develop and validate a HPTLC method for the simultaneous determination of aliskiren hemifumarate and valsartan in tablet dosage form.

10. To develop and validate a simultaneous equation method for the estimation of aliskiren hemifumarate and amlodipine besilate in tablets.

11. To develop and validate an absorbance ratio (Q analysis) method for the simultaneous determination of aliskiren hemifumarate and amlodipine besilate in tablets.

12. To develop and validate a first-derivative (zero crossing) spectroscopic method for the simultaneous determination of aliskiren hemifumarate and amlodipine besilate in tablets.

13. To develop and validate a RP-HPLC method for the simultaneous determination of aliskiren hemifumarate, amlodipine besilate and hydrochlorothiazide in combined tablet dosage form.