Chapter 3

Aim of Present Work
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Diabetes mellitus, a multi organ disease, is the most prevalent in people throughout the world. There are rapidly increasing number of drug groups available to treat high sugar level. Each group works through a different mechanism. That often allows multiple drugs to be used simultaneously as we take advantage of their different, but complimentary properties.

In the current scenario most of all the manufacturing units have sophisticated instruments like UV, HPLC and HPTLC; it is advantage that we can develop sensitive methods to determine anti-diabetics in combined dosage forms using these instruments.

On detailed literature survey, it was found that though individually these drugs have been analyzed by many methods, but very few methods have been reported for the simultaneous determination of anti-diabetic drugs in combination. Therefore, it was thought of interest to develop precise, accurate, simple, economic, reliable analytical methods and validate these developed analytical methods as per ICH guideline for the estimation of these drugs in pharmaceutical dosage forms.

The specific aim of the research was

- To develop and validate HPTLC methods for simultaneous estimation of anti-diabetics in pharmaceutical dosage forms
- To develop and validate HPLC methods for simultaneous estimation of anti-diabetics in pharmaceutical dosage forms
- To carry out force degradation study of some anti-diabetics using HPLC methods
- To develop and validate spectrophotometric methods for simultaneous estimation of anti-diabetics in combination using simultaneous equation method and absorption correction method
- All of the above mentioned methods was developed and validated statistically to ensure their accuracy, precision, repeatability, reproducibility and other analytical method validation parameters as mentioned in ICH guidelines
Research Plan

Design of study:

From the literature survey, some antidiabetic drugs were selected. Then analytical methods like spectrophotometric methods and chromatographic methods like HPLC, HPTLC were tried for development on the basis of trial and error. The developed methods were checked for analysis of marketed formulations. All the developed methods were validated as per ICH guideline Q2B [221] for the routine use in analysis of marketed formulations. Stability study of some drugs was carried out in different conditions of environment.

Plan of work:

1) Literature survey about the information of these drugs
2) Procurement of pure standard drug samples
3) Trial of developed methods on pure drug samples which includes following steps-
   a) High Performance Thin Layer Chromatography:
      - Selection and optimization of mobile phase
      - System suitability parameters study
   b) High Performance Liquid Chromatography:
      - Selection of column
      - Selection and optimization of mobile phase
      - Selection of chromatographic condition
      - System suitability parameters study
   c) UV Absorption Spectrophotometry:
      - Determination of detection wavelengths
      - Study of Beer-Lambert’s law
      - Determination of absorptivity values $A$ (1%, 1 cm) at selected wavelengths
4) Analysis of standard laboratory mixture to see feasibility of developed method
5) Validation of developed methods
6) To adopt selected methods on formulation
7) Analysis of validation data was performed by using statistical tests

8) All the developed methods were compared by using statistical tests

Stability study of some drugs was carried out in different conditions. As per ICH guideline Q1A (R2) [222]; different stress studies were selected.