Chapter-3

3. SCOPE, OBJECTIVE AND PLAN OF WORK

A drug is defined as a substance used for diagnosis, cure, improvement, prevention or management of diseases in human beings or animals or for alternating any structure or function of the body of human being or animals. Pharmaceutical chemistry\(^{1-4}\) is a science that makes use of common laws of chemistry used to study drugs i.e., their preparation, chemical natures, composition, structure, affect on an organism and the studies the physical and chemical properties of drugs, the quality control methods and the storage conditions etc. The branch of drugs may be generally classified as:

1. Pharmacodynamics agents
2. Chemotherapeutic agents

It is essential to find the content of individual drug either in bulk or single or combined dosage forms for testing for purity. This is also important to know the drug concentration and it metabolites in biological fluids after taking the dosage form for the management. The chief purpose for that is to improve the conditions and parameters which should be followed in the development and validation of a proposed method.

A survey of literature reveals that some analytical methods are not available for the drugs like Dapagliflozin, Alogliptin, Orlistat and Gliclazide. Even though very little methods of determination of above drugs are available, many of them experience from one disadvantage or the other, such as lack of selectivity, simplicity and low sensitivity etc. Dapagliflozin, which is a selective sodium-glucose co-transporter subtype 2 (SGLT2) inhibitor with activity of anti-hyperglycemic. It is selectively and potently inhibits the SGLT2 compared to the SGLT1, which is the glucose co-transporter found in the gut. Alogliptin is a orally bioavailable, pyrimidine dione-based inhibitor of dipeptidyl peptidase-4 (DPP-4) enzyme, with activity of hypoglycemic. In addition to its effect on glucose levels, Alogliptin may inhibit inflammatory responses by preventing the toll-like receptor 4 (TLR-4)-mediated formation of pro-inflammatory cytokines. Orlistat is a lipase inhibitor for obesity management that acts by inhibiting the dietary absorption of fats. It works by the pancreatic lipase inhibition, an enzyme that breaks down fat in the intestine. Without this enzyme, fat from the diet is excreted undigested and not absorbed by the body. It is a reversible active-site inhibitor of gastrointestinal lipases. Gliclazide is a 2\(^{nd}\) generation sulphonyl urea which acts as a hypoglycemic drug. It stimulates beta cells of the islet of Langerhans in the pancreas to release the insulin hormone. It also enhances the peripheral sensitivity of insulin. The presented physicochemical methods are insufficient to meet the requirements. Hence it is proposed to get better the existing methods and to develop a new
method for the assay of Dapagliflozin, Alogliptin, Orlistat and Gliclazide in pharmaceutical dosage forms.

3.1. OBJECTIVE
According to the literature survey it was found that few analytical methods such as (HPLC, UV-Visible analysis and HPTLC) were reported for the estimation of Dapagliflozin, Alogliptin, Orlistat and Gliclazide. The objective of the proposed method is to develop simple and accurate methods for the determination of Dapagliflozin, Alogliptin, Orlistat and Gliclazide by RP-HPLC methods in pharmaceutical dosage forms.

3.2. The plan of the proposed work includes the following steps:
1. To undertake solubility and analytical studies of Dapagliflozin, Alogliptin, Orlistat and Gliclazide and to develop initial chromatographic conditions.
2. Setting up of initial chromatographic conditions for the assay of Dapagliflozin, Alogliptin, Orlistat and Gliclazide in pure and pharmaceutical dosage forms.
3. Optimization of initial chromatographic conditions.
4. Analytical method validation of the developed HPLC methods.
5. Evaluation of analytical method validation report generated for the developed methods.