3. OBJECTIVES

Now a days there is increase in the lifestyle related disease mainly cancer and cardiovascular diseases therefore one finds it important to maintain quality of the life saving drugs like anti-cancer drugs, therefore it has been decided to develop validated analytical methods for anti-cancer like anastrozole and Temozolomide and their impurities and degradants.

Based on the literature, there are very few analytical methods have been established for the quantitative estimation of the determination of Anastrozole [6] and Temozolomide [7] in bulk as well as in their formulations. The methods have been reported for the quantification of Anticancer Drugs in human plasma. Hence there is necessity for development of newer, efficient and economical analytical methods for estimation of Anticancer Drugs in bulk drug and pharmaceutical dosage forms.

The analytical method development for the detection, identification, quantitative determination of impurities using various analytical techniques may offer various advantages such as improving drug product quality and manufacturing efficiency of the drug product.

Estimation of impurity level and validation study of drug product has received considerable attention in the recent past due to growing interest in the cost effective and quality drug product. Considering the great opportunities which exist for the discovery and development of new formulation, ‘Quality’ would be today’s basic need. The present study might be the best way to evaluate the quality and stability of the pharmaceutical formulations. Therefore quality issues such as the studies of impurity, stability, degradation and analysis of drug product would be the research work to stress upon.

- Development of new, simple, accurate and economical and simultaneous analytical methods for the estimation of Anastrozole and Temozolomide in bulk Drugs.
- Development of HPLC method for determination of assay and related substances simultaneous analytical methods for Anastrozole and Temozolomide in marketed formulations.
- Analyze the marketed formulation to determine the content of Newer Anticancer drugs in commercial formulation.
- Assay and related substances of drug in dosage forms.
- Standardize the developed method in accordance with USP and ICH guidelines.
- Development of Bio-analytical methods on LC/MS/MS for the estimation of Anastrozole and Temozolomide in bulk as well as in their formulations.
- Validation of Bio-analytical methods on LC/MS/MS using plasma samples.
Drugs analysis means identification, characterization and determination of drugs. The number of drugs introduced into the market has been increasing at an alarming rate. These drugs may be new entities in the market or structural modifications of the existing drug. Newer analytical methods are developed for these drug combinations because of the following reasons:

- The drug or drug combination may not be official in any pharmacopoeia.
- The literature search was not revealing an analytical method for the drug or its combinations.
- Analytical methods may not be available for the drug combination due to the interference caused by recipients.
- Newer methods are also recommended by Research Institutions.
- Newer methods are also recommended Quality control Department in Industries Approved Testing Laboratories.