

Chapter II

Objectives of the study

2.1. General Objectives

This topic for the research work is selected based on the increasing needs of the pharmaceutical industry in development and validation of suitable analytical methods for the pharmaceuticals. Among the various other available analytical techniques, the scope of work was focused on the different chromatographic techniques such as HPLC and LC-MS which are accurate, precise and rapid techniques and are having wide spectrum of application in pharmaceutical industry. Literatures were reviewed and there is a need to develop new, simple, specific, reliable analytical methods for Riluzole hydrochloride, Aprepitant, Rimonabant hydrochloride, Ropinirole hydrochloride and orlistat. To establish the well qualified methods, the analytical scientist should take the aid of sophisticated analytical instruments for various applications such as

2.1.1. Objectives of Development and validation of bio analytical methods

The development of sound bio analytical method is of paramount importance during the process of drug discovery and development culminating in a marketing approval. Bio analysis, employed for the quantitative determination of drugs and their metabolites in biological fluids, plays a significant role in the evaluation and interpretation of bioequivalence, pharmacokinetic (PK), and toxic kinetic studies. Selective and sensitive analytical methods for quantitative evaluation of drugs and their metabolites are critical for the successful conduct of pre-clinical and/or bio pharmaceuticals and clinical pharmacology studies. So there is a need of present research work to develop and validate a bio analytical method for the pharmaceuticals.

2.1.2. Objectives of Quantitative and qualitative analysis

As we know that for every product going to be released or available in the market requires 100% quality and with reported quantity. Without quality and quantity no product will survive in the market. The same can be applied for a pharmaceutical which is very important in our daily life to save human life. It is challenging for a pharmaceutical industry to produce a quality pharmaceutical with reported labeled quantity of active pharmaceutical ingredient. So the demands are increased for pharmaceutical industry in developing suitable analytical methods for the pharmaceuticals to ensure their quality and quantity. The need of present research work was to ensure the quality and quantity of pharmaceuticals in bulk and pharmaceutical dosage forms using sophisticated analytical techniques. Among the various other available techniques, the objective of work was focused on the modern chromatographic technique such as HPLC which was accurate, precise and sophisticated technique and having vast spectrum of application in pharmaceutical industry. The present research focused to perform the qualitative and quantitative analysis irrespective of the therapeutic agent and no matter that it was present as individual or else in the combination with other drugs.

2.1.3. Objectives of Stability indicating assays (Degradation studies)

If you look at the label on your favorite prescription or over the counter pharmaceutical product, you'll see a use before date. Before this date, the product should remain fully effective under normal storage conditions. The product's shelf life is determined using standardized storage conditions of controlled temperature and humidity. This can be translated into accepted

product lifetimes. To determine this shelf life, you must measure two different aspects of the drug after it has been stressed. First, determine its potency, or the amount of active ingredient. It is easy to understand that a significant loss in the amount of active ingredient would make a drug less effective. This measurement is fairly simple because relatively speaking; a large amount of drug is present. Second, determine the degradants or impurities that appear as a result of aging. This determination is much more difficult, because you must anticipate what degradants might be present, and you must measure all degradants that appear at concentrations of more than 0.1% of the parent drug. This portion of the assay falls in the realm of trace analysis. According to current good manufacturing practices, all drugs must be tested with a stability-indicating assay before release. The U.S. Food and Drug Administration (FDA) define a stability-indicating assay as follows: "A stability indicating assay is a validated quantitative analytical procedure that can detect the changes with time in the pertinent properties of the drug substance and drug product. A stability-indicating assay accurately measures the active ingredients, without interference from degradation products, process impurities, excipients, or other potential impurities."

Forced degradation or stress testing is undertaken to demonstrate specificity when developing stability-indicating methods, particularly when little information is available about potential degradation products. So there is a need of present research work was to monitor the stability of bulk and pharmaceutical dosage forms using sophisticated analytical techniques. Among the various other available techniques, the researchers focused on the modern chromatographic technique such as HPLC which was accurate, precise and

sophisticated technique and having vast spectrum of application in pharmaceutical industry.

2.2. Plan of work

2.2.1. Selection of drugs

We have selected five (05) novel therapeutic agents based on the potency (drugs having label claim less than 100 mg). The details of the drugs and their label claim was furnished below as follows

Table 6: Drugs selected for the work

Drug	Label claim (mg)
Riluzole	50
Rimonabant Hydrochloride	20
Aprepitant	80
Ropinirole Hydrochloride	2
Orlistat	60

The present study is carried out to develop a simple, rapid, selective methods for estimation (Assay & Stability Assay) of Riluzole hydrochloride, Aprepitant, Rimonabant Hydrochloride, Orlistat and Ropinirole Hydrochloride by High performance liquid chromatography (Reverse phase)

The work also extended to develop a bio analytical method by LC/MS/MS method for the determination of Riluzole in human Plasma.