CHAPTER I

Introduction

This chapter gives a brief account of spectrophotometric methods of pharmaceutical analysis along with various statistical parameters employed in the present investigation. The list of drugs and reagents selected for the present study is also given in this chapter. Last part of the chapter outlines the scope of the proposed research work.
Mankind owes much to pharmaceutical chemistry, the chemistry of drugs, medicinal and pharmaceutical products. The word "drug" has been derived from the French word "drogue", which means a "dry herb". It is defined as any substance or product that is used or intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient. The main objective of this has been to improve the quality of life of human beings. A large number of bioactive compounds are available in the form of pharmaceutical formulations to control diseases. The discovery of many new drugs has helped in the successful eradication and/or control of many deadly diseases. In the past, several pharmaceutical chemists have explored numerous approaches for finding and developing organic compounds that are now available in pharmaceutical preparations suitable for the treatment of diseases and often for the maintenance of human health. But in recent years, more and more synthetic organic and inorganic compounds are being used as drugs for the treatment of diseases.

Classification of drugs:

The drugs may be classified into two categories based on their therapeutic actions:

1. Chemotherapeutic agents:

   The term "chemotherapy" was coined by German chemist, Paul Ehrlich in 1891. It is a specific treatment using chemical agents to arrest the progress or eradicate diseases caused by microorganisms like bacteria, virus, helminths, fungi, protozoa, spirochates, etc., without affecting the healthy tissues in the body of the recipient. The agents so used are called chemotherapeutic drugs. These include organometallic compounds, antitubercular, antifungal, antibacterials, antineoplastics, anthelmintic, antimalarials, antisepsics, antileprotics, antiprotozoals, birth control and antiviral drugs.

2. Functional or Pharmacodynamic agents:

   These are the drugs, which act on various functions of body, but are not specific remedies for particular diseases. Some pharmacodynamic agents include central nervous system modifiers (depressants and stimulants),
Adrenergic stimulants and blocking agents, cholinergic and anticholinergic agents, antihistamines, cardiovascular agents, diuretics, local anaesthetics, haematological agents etc.

Assay:

The determination of the potency of the active principle in the unit quantity of medicinal preparation is known as "Assay" and it may be divided into three classes as shown below:

1. Chemical assay: The potency of the active principle present in the drug preparations is determined by chemical methods.

2. Bio assay: It is the method of determination of the potency of a physical, chemical or biological agent by means of a biological indicator.

3. Immunological assay: This is based on the principle that a hormone antigen reacts with its specific antibody.

However, chemical assay is more reliable and precise than the biological and immunoassay.

Analytical chemistry has had a big role to play in the quality assurance and control of bulk drugs and their dosage forms. Many instrumental techniques have been added to penetrate chemical estimations not only of the active ingredient(s) but also the quantification of related compounds or impurities in incoming chemicals, drug materials and formulations. Pharmacopoeal standards are promulgated by government agencies in all countries, and are called "pharmacopoeia". The official monographs for the drugs and their formulations are both descriptive and informative in addition to prescribing standards for products and conditions for their storage.

The drugs and their formulations are determined by means of physical, chemical, physico-chemical and biological methods. Physical and physico-chemical methods are most useful. Physical methods of analysis are based on the physical properties of a substance such as colour, solubility, moisture content, melting point (for solid substance), degree of turbidity or transparency, density or specific gravity, freezing and boiling points (for liquids). Chemical methods of analysis include volumetric and gravimetric methods.
procedures, which are based on complex formation, precipitation, acid-base and redox reactions. Physico-chemical methods depend on the physical phenomena that occur as a result of chemical reactions.

The last two decades have witnessed an exciting phase in the field of Analytical Chemistry in terms of new and improved techniques, which permit detection and quantification of drugs in bulk samples, pharmaceutical formulations and in biological samples. The analytical methods have advantages not only in consumption of small quantity of analyte, reagents and less time required but also that the results are very accurate. An important feature of modern pharmaceutical chemistry is the introduction of more refined and sensitive methods of physico-chemical analyses such as optical (atomic absorption spectrophotometry, emission and fluorescence methods, polarimetry, photometry including photocolorimetry and spectrophotometry covering UV, visible and IR regions or turbidimetry), electro-chemical (coulometry, conductometry, polarography, potentiometry, voltammetry and amperometry) and chromatography (thin layer, HPLC, LC, HPTLC, GC and CEC) have been specifically used for the assay of individual components of a mixture. Other analytical techniques including kinetic-spectrophotometric, electrophoresis, thermal and flow injection methods are also being used for the assay of drugs. In addition, NMR technique is also used for the assay of individual components of a mixture. The combination of mass spectrometry with gas/liquid chromatography is one of the most powerful tools employed in identification and quantification of analyte in bulk or dosage forms.

With ever-growing demands on drug specificity to fight against new illness, number of newer drugs are being pushed into the market at such a great pace that it has become difficult to keep abreast of their merits and demerits. Consequently, a strict control on the quality of the drugs and their therapeutic actions is very important. Hence, modern pharmaceutical chemistry focuses on the introduction of more refined and sensitive physico-chemical analysis, which
meet the following requirements.

- The analysis should take a minimal time
- The cost of analysis should be minimum
- Precision and selectivity of the method should be good
- The accuracy of the analysis should fulfill the requirements of pharmacopoeia

These requirements are met by physico-chemical methods of analysis, a merit of which is their universal nature that can be employed for analyzing various class of drugs. The existing methods also often need improvements to suit laboratory requirements and facilities available in a particular laboratory set up. Even though, modern methods of analysis (HPLC, GLC, NMR and Mass) for purity assay afford simplicity, speed, good specificity and excellent precision and accuracy, they involve sophisticated equipments, which are not in the reach of most laboratories and small-scale industries. Moreover, they pose problems of maintenance.

Among various techniques, spectrophotometry still plays a significant role in the determination of compounds at micro or nanogram levels. It is simple, economically viable and easy to carryout. Its importance lies in the chemical reactions upon which the procedures are based, rather than upon the sophistication of the instrument. Many reactions involving formation of coloured species for a particular drug are quite selective or can be rendered selective through the introduction of masking agents, control of pH, use of solvent extraction techniques, adjustment of oxidation states or by prior removal of interfering substances. Hence, spectrophotometry is generally preferred in small-scale industries and in most of the laboratories for routine quality control.
THEORY OF SPECTROPHOTOMETRIC METHOD:

The act of identifying materials based on their colour was probably one of the earliest examples of qualitative molecular absorption spectrophotometry. The method is remarkable for its versatility, sensitivity and precision.

The variation of the colour of a system with change in concentration of some component provides the basis of spectrophotometric method, which shows the simple relationship between the absorption of radiation by a solution and the concentration of the coloured product(s) in the solution. A close relationship exists between the colour of a substance and its electronic structure. A molecule or ion exhibits absorption in the visible or UV region when the radiation (photons) causes an electronic transition in molecules containing one or more chromophoric groups. The colour of such a molecule may be intensified by substituents called auxochromes (e.g. -SH, -NH₂, -OH), which displace the absorption maxima towards longer wavelength (bathochromic shift).

**Beer-Lambert law:**

This is the fundamental law governing the absorption of all types of electromagnetic radiation and is known variously as the Lambert-Beer, Bouguer-Beer or Beer's law. This basic law of spectrophotometry is expressed by the equation

\[ \log \frac{I_0}{I} = εbc = A \]

where

- \( I_0 \) = radiant power of the beam striking the sample
- \( I \) = radiant power of the beam transmitted by the sample
- \( b \) = thickness of the absorbing sample in cm
- \( c \) = concentration of the absorbing constituent of the sample expressed in moles/litre
- \( ε \) = a constant, extinction coefficient, whose value depends on the identity of the absorbing species, the wavelength of the light, the nature of the solvent, the temperature etc., is called the molar absorptivity. Units of \( ε \) are \( 1 \) \( \text{mol}^{-1} \) \( \text{cm}^{-1} \)

Chapter I
The above equation indicates that the absorbance of a solution is directly proportional to the concentration of absorbing species when the length of light path is fixed and directly proportional to light path when the concentration is fixed.

It is evident that a plot of absorbance at constant ‘b’ against concentration gives a straight line if Beer’s law is obeyed. This line passes through the origin, since any absorption due to the solvent is cancelled out in the usual method of making the measurement.

**Calibration curve:**

The common method of using a spectrophotometer involves the construction of a calibration curve for a constituent to be determined. For this purpose, suitable quantities of the constituent are taken and treated in exactly the same way as the sample solution for the development of the colour and the measured absorbance values are plotted against the concentration of the constituent. If Beer’s law is followed, a straight line passing through the origin will be obtained.

**Ringbom’s plot:**

Ayers has pointed out that a straight line obtained in a Beer’s law curve does not give directly the concentration range within which accurate determination of the coloured product is possible. The optimum range for maximum precision is evaluated by plotting absorbance (100-percent transmittance) against the log of the drug concentration (Ringbom’s plot). A ‘S’ shaped curve is obtained with the optimum range for accurate determination indicated by the linear portion of the curve with maximum slope.

**Sensitivity of a spectrophotometric method:**

Sensitivity refers to the slope of a calibration curve, but is frequently used to mean the least determinable concentration or amount of the species to be determined. The numerical expression of the sensitivity of spectrophotometric
methods is the molar absorptivity ($\varepsilon$) at the wavelength of maximum absorbance ($\lambda_{\text{max}}$) of the coloured species

$$\varepsilon = \frac{A}{bc}$$

The molar absorptivity is a valuable index in evaluating the relative sensitivity of various available spectrophotometric methods.

For sensitive spectrophotometric methods, $\varepsilon$ is greater than $1 \times 10^4 \text{ mol}^{-1} \text{ cm}^{-1}$ and the values of $\varepsilon$ below $1 \times 10^3 \text{ mol}^{-1} \text{ cm}^{-1}$ correspond to less sensitive methods. The sensitivities of spectrophotometric methods for the drug to be determined can be compared in terms of $\varepsilon$. In order to make a comparison, which is independent of atomic weights, the sensitivity is often expressed in terms of sensitivity index given by Sandell, which represents the number of micro/nanogram of the determinant per ml of a solution having the absorbance of 0.001 for a path length of 1 cm. Sandell’s sensitivity (SS) is expressed in $\mu$g cm$^{-2}$ or ng cm$^{-2}$.

In the determination of $\varepsilon$, the absorbance measured should be within the range over which the coloured species obeys Beer’s law. In addition, the slit width used is of importance. Sensitivity also depends on the monochromaticity of the radiation. With monochromatic light of very narrow bandwidth corresponding to the wavelength of $\lambda_{\text{max}}$, the maximum value of molar absorptivity (at $\lambda_{\text{max}}$) is obtained.

**Theory of solvent extraction:**

Solvent extraction, often termed as liquid-liquid extraction, is considered to be the most versatile, popular and elegant method amongst the various separation techniques. The major advantage of this method is that the separation is achieved on macro to micro levels. The distribution of a solute in a certain ratio between two immiscible solvents, aqueous and organic phase, is the basic principle of liquid-liquid extraction. In limiting cases, the solute can be more or less transferred into the organic phase. The technique has proved to be an indispensable in inorganic-analytical and pharmaceutical chemistry for quantitative separation and determination.
Ion-association complex extraction has been applied for the estimation of numerous compounds possessing basic moieties (secondary or tertiary aliphatic amino groups) using a suitable acid dye as a reagent and a chlorinated solvent as an extractant. The physical forces such as dipole and induced dipole interactions, London dispersion forces, hydrogen bonding and dative bonding interactions lead to the formation of molecular complexes, which exist in solutions in equilibrium with their components. However, molecular complexes can be readily detected because of the differences in physical properties such as, absorption spectra and solubility in organic solvents from those of the pure components. The ion-association complex or adduct is a special form of molecular complex resulting from two components which is extractable into organic solvents from aqueous phase at suitable pH. Out of the two, one component is a chromogen (dye or drug complex) possessing either cationic or anionic charge and so insoluble in organic solvents whereas the other is colourless, possessing opposite charge (anionic or cationic) to that of chromogen.

The choice of a solvent for extraction is governed by the following considerations:

- A high distribution ratio for the solute and a low distribution ratio for undesirable components
- Low toxicity and inflammability
- Low solubility of the interested component in the aqueous phase
- Sufficiently low viscosity and sufficient density difference from the aqueous phase to avoid the formation of emulsions

Sometimes mixed solvents may be used to improve the above properties. Salting out agents may also improve extractability.

The method of least squares:

Least-squares regression analysis⁴⁶,⁴⁷ used to describe the relationship between the response say absorbance (y) and concentration (x), can be
represented by the general function:
\[ y = f(x, a, b_1, \ldots, b_m) \]
where \( a, b_1, \ldots, b_m \) are the parameters of the function.

The convention that the \( x \) values relate to the controlled or independent variable (e.g. the concentration of a standard) and the \( y \) values to the dependent variable (the absorbance measurements) is adopted generally. This means that the \( x \) values have no error on the condition that errors made in preparing the standards are significantly smaller than the measuring error. The values of the unknown parameters \( a, b_1, \ldots, b_m \) must be determined in such a way that the model fits the experimental data points \((x_i, y_i)\) to the best possible.

The true relationship between \( x \) (say concentration) and \( y \) (say absorbance) is considered to be given by a straight line. The relation between each observation pair \((x_i, y_i)\) can be represented as
\[ y_i = \alpha + \beta x_i + e_i \]
The signal \( y_i \) is composed of a deterministic component predicted by linear model and a random component \( e_i \). One must now find the estimates \( a \) and \( b \) of the two values \( \alpha \) and \( \beta \). This is done by calculating the values of \( a \) and \( b \) for which \( e_i^2 \) is minimal. The component \( e_i \) represents the differences between the observed \( y_i \) values and the predicted \( y_i \) values by the model. The \( e_i \) values are called the residuals, and \( a \) and \( b \) are the intercept and slope respectively.

\[
a = \frac{n \sum_{i=1}^{n} x_i y_i - \sum_{i=1}^{n} x_i \sum_{i=1}^{n} y_i}{n \sum_{i=1}^{n} x_i^2 - \left( \sum_{i=1}^{n} x_i \right)^2}
\]

\[
b = \frac{\sum_{i=1}^{n} y_i \sum_{i=1}^{n} x_i^2 - \sum_{i=1}^{n} x_i \sum_{i=1}^{n} x_i y_i}{n \sum_{i=1}^{n} x_i^2 - \left( \sum_{i=1}^{n} x_i \right)^2}
\]
Correlation coefficient, \( r \):

The correlation coefficient \( r (x, y) \) is useful to indicate the relationship between the chosen scales. Correlation coefficient is calculated by the equation,

\[
r = \frac{n \sum_{i=1}^{n} x_i y_i - \left( \sum_{i=1}^{n} x_i \right) \left( \sum_{i=1}^{n} y_i \right)}{\sqrt{\left( n \sum_{i=1}^{n} x_i^2 - \left( \sum_{i=1}^{n} x_i \right)^2 \right) \left( n \sum_{i=1}^{n} y_i^2 - \left( \sum_{i=1}^{n} y_i \right)^2 \right)}}
\]

where, \( x_i \) and \( y_i \) are the individual values of the variables \( x \) and \( y \), and \( n \) refers to the number of observations. The value of \( r = 1 \) indicates the exact correlation between the true variables while \( r = 0 \) indicates the complete independence of the variables. The \( r > 0.99 \) indicates excellent linearity.

Precision and accuracy:

The idea of carrying out a determination is to get a valid estimate of a 'true' value. When one considers a certain criteria, according to which an analytical procedure is selected, precision and accuracy are usually the first to come to the mind. Precision and accuracy together determine the error of an individual determination. They are among the most important criteria for judging any analytical procedure.

**Precision:**

The term precision\(^\text{48}\) is used to describe the reproducibility of the measurements. It can be defined as the agreement between the numerical values of two or more measurements that have been made in identical fashion. One of the most common statistical terms employed is the standard deviation of a population of observations. The standard deviation (\( S \)) is the square root of the sum of squares of deviations of individual results (\( x_i \)) from the mean (\( x \)) divided by one less than the number of results in the set. It is calculated by

\[
S = \sqrt{\frac{\sum_{i=1}^{n} [x_i - x]^2}{n - 1}}
\]

Standard deviation has the same units as the property being measured.
The square of standard deviation is called the variance \( (S^2) \). Relative standard deviation is the standard deviation expressed as a fraction of the mean, \( S/x \). It is sometimes multiplied by 100 and expressed as a percent relative standard deviation to make it a more reliable expression of precision.

\[
\text{% Relative standard deviation} = \frac{S \times 100}{x}
\]

**Accuracy:**

Accuracy is the nearness of a measurement or result to the true value. It is expressed in terms of error. Accuracy normally refers to the difference between the mean, \( x \), of a set of results and the true or correct value for the quantity measured. According to IUPAC, accuracy relates to the difference between a result (or mean) and the true value.

For analytical methods, there are two possible ways of determining the accuracy \textit{viz.} absolute method and comparative method.

**Absolute method:**

The test for accuracy of the method is carried out by taking different amounts of the constituent and proceeding according to the specified instructions. The difference between the mean of an adequate number of results and the amount of constituent actually present, is usually expressed as parts per hundred (\%) i.e. % error.

The constituent in question will usually have to be determined in the presence of other substances and it will therefore be necessary to know the effect of these upon the determination. This requires testing the influence of a large number of probable compounds in selected samples, each in varying amounts. In few instances, the accuracy of the method is controlled by separations (usually solvent extraction or chromatographic technique) involved.

**Comparative method:**

In the analysis of pharmaceutical formulations or synthetic mixtures (laboratory made) of desired composition, the content of the constituent is determined by two or more (proposed and standard/reported methods) supposedly "accurate" methods. These methods, of essentially different
character, can be accepted usually as indicating the absence of an appreciable
determinate error. The general procedure for the determination of above
samples either in the proposed or standard/reported methods comprises of
various operations which include sampling, preparation of solutions, separation
of interfering ions/substances, if any, and also proposing a method for
quantitative determination.

Evaluation of precision and accuracy by comparison of two procedures59:

In order to check the accuracy of the proposed method, one often
compares the proposed method or 'test method', with an existing
(standard/reported) method, called the 'reference method'.

Student t-test:

Student t-test is used to compare the means of two related (paired)
samples analyzed by reference and proposed methods. It gives answer to the
correctness of the null hypothesis with a certain confidence such as 95% or
99%. If the number of pairs (n) are smaller than 30, the condition of normality
of x or at least the normality of the difference \( (d_i) \) is required. If this is the case
the quantity

\[
 t = \frac{d}{S_d / \sqrt{n}}
\]

The calculated "t" values are compared with the tabulated value for a
given number of replicates at the desired confidence level. If the calculated
t values are smaller than the tabulated t values, one can conclude that the two
methods are not significantly different at a given confidence level.

F-test:

The significance of the difference in variances of reference and proposed
methods can be tested by F-test. Suppose that one carries out \( n_1 \) replicate
measurements using proposed method and \( n_2 \) replicate measurements using
reference method. If null hypothesis is true, then the estimates \( S_T^2 \) (variance of
proposed method) and \( S_R^2 \) (variance of reference method) do not differ very
much and their ratio should not differ much from unity. In fact, one uses the
ratio of the variance

\[ F' = \frac{S_L^2}{S_R^2} \]

It is conventional to calculate the F-ratio by dividing the large variance by the smallest in order to obtain a value equal or larger than unity. If the calculated F-values are smaller than the tabulated F-values, one can conclude that the procedures are not significantly different in precision at a given confidence level.

**Confidence limits:**

Calculation of the standard deviation for a set of data provides an indication of the precision inherent in a particular procedure or analysis. But, in the absence of a large number of observations/measurements, it is difficult to know the nearness between experimentally determined mean value (x) and to the true mean value (μ). Statistical theory however allows us to estimate the range within which the true value might fall, within a given probability defined by the experimental mean and the standard deviations. This range is called the confidence interval and the limits of this range are called the confidence limit:

\[ \text{Confidence limit} = x \pm \left[ \frac{t s}{\sqrt{N}} \right] \]

where, t is a statistical factor that depends on the number of degrees of freedom and the confidence level desired, s/√N is the standard deviation of the mean, N number of replicates and x is the mean value.

**Recovery experiments (Standard addition method):**

Recovery studies were conducted by analyzing each pharmaceutical formulation in the first instance for the active ingredient by the proposed methods. A known amount of the drug to be determined was added to each one of the previously analyzed samples and the total amount of the drug was once again determined by the proposed methods. The amount of the added drug was determined by the difference. Satisfactory recovery values will enhance the accuracy of the proposed procedures.
Stoichiometry of the complexes:

Spectrophotometric data are used to determine the empirical formulae of complexes formed by the analyte and the reagents in solution state. The most extensively used spectrophotometric methods for the determination of composition of the complexes are Job's method of continuous variations, mole ratio method, slope ratio method, equilibrium shift method and logarithmic method. In the present investigation, Job's method of continuous variations was employed.

*Job's method of continuous variations:*

Job's method of continuous variations, a simple and widely used method for determining the composition of the complexes, is based on the variation of absorbance of the drug and the reagent of equimolar concentrations keeping total volume of the drug and the reagent constant. A plot of absorbance *versus* the mole fraction of the drug in the mixture, \( f = \frac{[D]}{[D]+[R]} \) shows a maximum at the composition of the complex. If a 1:1 complex (DR) is formed, the curve shows a maximum at \( f = 0.5 \). If the composition of the complex is 1:2 (DR₂) the maximum occurs at \( f = 0.33 \) and if its formula is D₂R, the maximum is expected at \( f = 0.67 \) and so on.

*Chemistry of the coloured species formed:*

The chemistry of the coloured species formed in each method is ascertained either through probability with the existing experimental evidences or through analogy with the reported methods.

**DRUGS SELECTED FOR THE PRESENT STUDY**

The ever increasing use of various class of drugs for the treatment of different diseases makes their determinations a matter of foremost importance. The following drugs have been selected in the present work:

- **Dopamine hydrochloride** [TTK Pharma Ltd.].
- **Methyl Dopa** [Indian Drugs and Pharmaceuticals Ltd.].
- **Levodopa** [Sun Pharmaceuticals Ltd., India].
- **Pyrocatechol** [Merck].
Promethazine hydrochloride [Rhone-Poulenc (India) Ltd.].
Methdilazine hydrochloride [Glaxo (India) Ltd.].
Isothipendyl hydrochloride [German Remedies Ltd.].
Isoniazid [M/s Cadila Pharmaceuticals Ltd., India].
Piroxicam [M/s Cipla Pharmaceuticals Ltd., India].
Ceterizine dihydrochloride [Dr. Reddy’s laboratory, India].
Haloperidol [Torrent Pharmaceuticals Ltd., India].
Propranolol hydrochloride [M/s Cipla Pharmaceuticals Ltd., India].

REAGENTS USED IN THE PRESENT INVESTIGATION

The selection of a reagent for the determination of a particular drug is
made after a literature survey for methods that have been used or that shows
reasonable promise for the drug under consideration. If not enough information
is not found in this way, the reagent that acts most rapidly and stoichiometrically
can be chosen after investigation of the performance of plausibly selected ones
on a pure sample of the drug sought.

Different oxidizing agents, coupling agents, dyes, chemicals and also
drug samples employed as analytical reagents, in the present study are listed
below:

<table>
<thead>
<tr>
<th>Materials</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,2’bipyridyl</td>
<td>Merck</td>
</tr>
<tr>
<td>Ferric ammonium sulphate</td>
<td>s.d. fine chemicals Ltd., Mumbai, India</td>
</tr>
<tr>
<td>Bromopyrogallol Red</td>
<td>s.d. fine chemicals Ltd., Mumbai, India</td>
</tr>
<tr>
<td>O-Toluidine</td>
<td>Merck</td>
</tr>
<tr>
<td>1,10-phenanthroline</td>
<td>s.d. fine chemicals Ltd., Mumbai, India</td>
</tr>
<tr>
<td>Tiron</td>
<td>s.d. fine chemicals Ltd., Mumbai, India</td>
</tr>
<tr>
<td>Potassium per iodate</td>
<td>s.d. fine chemicals Ltd., Mumbai, India</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>s.d. fine chemicals Ltd., Mumbai, India</td>
</tr>
<tr>
<td>Thioridazine Hydrochloride</td>
<td>Torrent Pharmaceuticals, India</td>
</tr>
<tr>
<td>Prochlorperazine dimaleate</td>
<td>Sandoz (Ind) Pvt. Ltd.,</td>
</tr>
<tr>
<td>Thymol Blue</td>
<td>s.d. fine chemicals Ltd., Mumbai, India</td>
</tr>
</tbody>
</table>

Chapter I 16
SCOPE OF THE PRESENT WORK

With ever growing demand on the drug specificity to fight against new illness, the newer drugs are being introduced to the market at such a great pace that it has become difficult to keep abreast of their merits and demerits. Nevertheless a strict control on the quality of the drugs and their therapeutic actions is very important. For this purpose, pharmaceutical industries or drug regulatory authorities require new, sensitive and easy methods of analysis for routine quality assurance. These methods should be less time consuming, accurate, economical, precise, selective and sensitive. The survey of existing analytical methods reveals that not much attention was paid for the development of sensitive spectrophotometric methods for the assay of selected drugs. Hence, the investigator has made some attempts in this direction and succeeded in developing the following new spectrophotometric methods for the assay of selected drugs:

- A sensitive spectrophotometric method for the determination of physiologically active compounds in bulk and pharmaceutical preparations

Chapter I
New spectrophotometric methods for the assay of antiallergic drugs in pharmaceutical formulations

Sensitive spectrophotometric assay of isoniazid using tiron and potassium per iodate as reagents

Novel spectrophotometric methods for the determination of micro amounts of piroxicam in pure and pharmaceutical formulations

Extractive spectrophotometric method for the assay of ceterizine hydrochloride in pharmaceutical preparations and biological samples

Bromocresol Green and Bromothymol Blue as sensitive reagents for Spectrophotometric determination of haloperidol

Indirect spectrophotometric assay of propranolol hydrochloride using N-Bromosuccinimide and phenothiazine derivatives

The results of the proposed methods were compared with those of official/reported methods. In addition, the results were subjected to rigorous statistical data treatment.
REFERENCES


Chapter I


