Chapter-II
Survey of literature of selected drugs
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(a): Escitalopram

Various methods are developed in the literature for the determination of escitalopram in pharmaceutical formulations which includes, spectrophotometric method and RP-HPLC method, spectrophotometric method, Fluorimetric method and Liquid chromatography-electrospray ionization mass spectrometry method.

Santosh Vilashchand Gandhi et al have developed simple, accurate, precise, and sensitive ultraviolet spectrophotometric and reversed-phase high-performance liquid chromatographic (RP-HPLC) methods for simultaneous estimation of escitalopram oxalate (ESC) and clonazepam (CLO) in combined tablet dosage form. The spectroscopic method employs an absorbance correction method using 238.6 and 308 nm as 2 wavelengths for estimation with methanol and water as solvents. Beer's law is obeyed in the concentration range of 10.0–50.0 and 0.5–3.0 μg/mL for ESC and CLO, respectively. The RP-HPLC method uses a Jasco HPLC system with HiQ SiL C18 column (250 × 4.6 mm id) acetonitrile–0.005 M tetrabutylammonium hydrogen sulfate (55 + 45, v/v) as the mobile phase, and satranidazole as an internal standard. The detection was carried out using an ultraviolet detector set at 287 nm. For the HPLC method, Beer's
law is obeyed in the concentration range of 10.0–60.0 and 0.5–3.0 μg/mL for ESC and CLO, respectively. Both methods have been successfully applied for the analysis of the drugs in a pharmaceutical formulation. Results of analysis were validated statistically and by recovery studies.

Zhangg et al, have detected the absorbability of escitalopram oxalate tablets by UV spectrophotometry at a wavelength of 2348 nm and the recovery and dissolution of which were calculated. The linear range of escitalopram oxalate tablets was 2.5-30 mg/ml and its average recovery was 100.64%. The method is simple, accurate, reliable and suitable for the determination of the dissolution of escitalopram oxalate tablets.

(b): Primaquine

Various spectrophotometric method56, TLC densitometric and U.V, spectrophotometric method7 and electrophoresis method8-10 are reported in the literature for estimation of Primaquine in tablets formulations.

Prasad, R.N et al5 proposed a sensitive and specific spectrophotometric method for the estimation of primaquine and used to study the plasma kinetics of primaquine in Rhesus monkeys. It was observed that the drug completely disappeared from the plasma in 24 hours after a single oral dose. Its concentration in the plasma reached a peak at 2 hours of
administration. The mean absorption and elimination half-lives were 0.36 +/- 0.08 and 3.44 +/- 0.37 hours respectively.

Sastry, B.S et al\textsuperscript{6}, proposed a spectrophotometric method for the determination of primaquine at 510 nm, based on its reaction with 3-methyl-2-benzothiazolinone hydrazone (MBTH) in the presence of cerium (IV) to form a stable, pink coloured oxidative coupling product. The method is applicable in the presence of other antimalarial drugs and to pharmaceutical preparations.

Dwivedi, A.K et al\textsuperscript{7}, developed TLC densitometric and U.V, spectrophotometric estimation methods for the estimation of primaquine. These methods are also suitable for the estimation of 80/53 or primaquine in their dosage forms and bulk drug samples.

(c) Nortriptyline

Various methods are reported in literature for the estimation of nortriptyline which includes, spectrophotometric method\textsuperscript{11}, Dispersive liquid-liquid microextraction method\textsuperscript{12} HPLC method\textsuperscript{13-15} and photometric and fluorimetric detection\textsuperscript{16}
H. D. Revanasiddappa and B. Manju, proposed a sensitive spectrophotometric method for the determination of amitriptyline hydrochloride, nortriptyline hydrochloride and doxepin hydrochloride in pure and dosage forms. The method is based on the oxidative coupling of the drugs with 3-methylbenzothiazolin-2-one hydrazone in the presence of iron(III) chloride in 1 M hydrochloric acid. The commonly encountered excipients and additives do not interfere with the determinations. Results of the present method are comparable with those of official methods. The new method offers the advantage of simplicity and rapidity.
Objectives of the present investigation
Section (ii): (a) Objectives of the present investigations:

Quality is important in every product or service but it is vital in medicine as it involves life. Unlike ordinary consumer goods, there can be and there is no "second" quality in drugs. Quality control is a concept, which strives to produce a perfect product by series of measures designed to prevent and eliminate errors at different stages of production. As a matter of fact, it is built in from the time of inception of the thought to make a product, to the time, it is finally made and send out with an OK quality report. In popular practice, the quality of medicines or pharmaceutical products is assured through quality control. It is, therefore, essential that quality assurance department must adopt "Good Laboratory Practice" to ensure reliability of pharmaceuticals together with their careful control are our moral obligations arising from the humanism towards the sick human beings. Consequently, the manufactures and the control of drugs are very responsible and they need substantial knowledge of the science. The decision to release or reject a product is based upon one or two types of control action or combination of both. If the product is a single entity of high purity, the analytical data is the basis for decision but most of the time, the formulation is a physical mixture of several potent drugs. With the growth of pharmaceutical analysis involving complex instrumentations, providing
simple analytical procedures for complex formulations is a matter of foremost importance.

Drugs and pharmaceuticals play a very significant role in the present days for the prevention, control and curing of different kinds of human diseases. It is a common observation and the practical truth that a single drug of a particular composition is marketed in various brand names by different manufactures. The possibility of minor changes in the chemical composition and standard of the drug will have a profound effect on the physiological and biological activities of the patient. It is very much painful for the present days scientist in general and to the analytical pharmaceutical chemist in particular to note in the various dailies about the entry of the spurious and substandard drugs into market, which definitely will have an adverse effect on the human beings at large.

It is with this challenge in mind, the author has taken up her thorough investigations to evaluate the purity of the various drugs released into the market. The author has made an extensive survey of the chemical and biochemical literature to know whether the reports involving simple experimental techniques such as the spectrophotometric techniques are available for ascertaining the assay and purity of the drugs. It is the
observation of the author that not much attention is paid to simple and rapid spectrophotometric methods for the assay of drugs available in literature.

Various instrumental techniques (HPLC, GC, Fluorimetry, NMR, IR, UV and Visible regions) are available in the literature for the assay of drugs. These methods are either expensive or do not give reproducible. Usually spectrophotometric technique is simple and less expensive. The selectivity and sensitivity of the spectrophotometric methods depend only on the nature of chemical reactions involved in colour development and not on the sophistications of the experiment.

UV and Visible spectrophotometric methods are highly versatile, sensitive and reproducible. This made the author to develop new spectrophotometric methods for the estimation of selected drugs having varying used in pharmaceutical preparations.