ABSTRACT

Analytical method development and validation is a trend in the field of pharmaceutical analysis to determine the drug content in bulk and pharmaceutical dosage forms by using spectral and chromatographic techniques. The quantification of drugs is carried out by using sensitive analytical instruments like HPLC, HPTLC….etc. which gives the greater accuracy and precision at low level of quantification.

Determination of active medicament in terms of purity is essential in the department of quality control and quality assurance for the pharmaceutical dosage form, prior to its entry into market. Now a days, the potency of the drugs and efficacy playing a major role in patient compliance during therapy. No matter the therapeutic agent present as individual or else in the combination with other drugs, the amount of active ingredient at individual should comply with posology direction in order to achieve effective treatment. However, in recent decades there are lot of analytical methods have been established for the determination of medicament in quality control and quality assurance aspects.

There is a rapid advancement and developments in the field of pharmaceutical analysis by efficient chromatographic and spectral techniques have been evoked for the determination of drugs not only in bulk and pharmaceutical dosage forms but also in biological fluids. The quantification of drugs in biological fluids was carried out by using

sophisticated, sensitive analytical instruments like HPLC, HPTLC, and LC-MS.

Analyst plays important role in pharmaceutical industry as an analyst or bio analyst to get FDA approval to newer potent drugs by conducting clinical trials, studies on healthy human volunteers. The modern analyst having so many challenges to develop a method for a new potent drug and the developed method was validated as per FDA guidelines to get a rapid, sensitive, accurate, reproducible, newer validated method.

Hence the proposed methodology has been under taken to develop suitable and sensitive method with higher degree of priority towards determination of medicament in dosage forms than the existing methods.

Proposed methodology

- Selection of drugs which are potent and recently approved by FDA.
- Authentication of procured sample standards by determination of melting point and both spectral and chromatographic studies.
- Development of method with required parameters.
- Validation of developed methods as per FDA guidelines.
- Application of developed system in determination of drug in pharmaceutical dosage forms and biological fluids by HPLC.

Expected out comes

The proposed methodology may hold superior choice for the determination of medicament in dosage forms than traditional methods like spectroscopy.