Chapter-2

LITERATURE SURVEY
CHAPTER 2

Chapter – 2: Literature Survey

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CHAPTER 2

2.1 LITERATURE SURVEY

Today’s scenario the major task for pharmaceutical industry is to develop and produce new medicinally important compounds with safe and effective for the human health. So, majority of the pharmaceutical industry depend on the quantitative analysis of those medicinally important compounds with quality. Most of the quantitative analysis of medicinally important organic compounds can be analysed by using liquid chromatographic techniques such as HPLC and UPLC\textsuperscript{20-48}. These techniques are more feasible and user friendly to handle when proper methods available. Quite a lot of researches added their effort and reported many methods for different medicinally important drug substances and its pharmaceutical dosage forms.

The Quantitative estimation of four fluoroquinolones (i.e. ofloxacin, enoxacin, norfloxacin and ciprofloxacin) by HPLC in medicinally important forms and blood serum was reported by V. F. Samanidou et al.\textsuperscript{33} The reported mobile is ethyl nitrile, monohydroxymethane and 0.4M citricacid (7:15:58) and the detection at 275nm. The reported HPLC column was kromacil C8.

S. Siewert et al.\textsuperscript{70} reported an analytical methodology for routine estimation of Levofloxacin assay in clear blood cells and dialysis fluids by HPLC with fluorescence detection. The separation technique used to elute the analyte was a binary gradient by using the stationary phase as YMC Carbon18 (150x2mm) column.
A rapid reverse phase LC stereospecific methodology for the content of Levofloxacin in clear blood cells (plasma) and urine was reported by F.A. Wong et al.\textsuperscript{71} The main component separated by using Inertsil ODS-2 RP-HPLC column by using 330nm as detection wavelength. The eluent composition consists of 5mM copper sulfate containing L-isoleucine (10mM) and methanol.

Xinxing Gao et al.\textsuperscript{72} investigated a rapid LC procedure for the content of Levofloxacin in human clear blood cells to support in bioequivalence studies. The researchers were used JASCO HPLC system to separate Levofloxacin from human plasma by using the Kromasil C-18 support with the help of eluent having mixture of ethyl nitrile, water, H\textsubscript{3}PO\textsubscript{4} and N,N-diethylethanamine. The detection wavelength used was 294nm.

L. Devi M. and Chandraskehar K.B.\textsuperscript{73} were validated a methodology of reverse phase LC procedure with gradient elution mode for the content of Levofloxacin in occurrence of impurities. The authors reported the gradient elution technique by using phosphate buffer and methanol.

M. Saeed Arayne et al.\textsuperscript{74} optimized a LC methodology for Levofloxacin content by using Multivariate Calibration Technique in API, pharmaceutical dosage forms and human plasma. The reported eluent contains mixture of phosphate solution (pH 2.9) and ethyl nitrile (6:5) by using Nucleosil C18 column. The detection was made at five wavelengths i.e. 260, 265, 270, 275 and 280nm and also an internal standard was used i.e. propylparaben.
A HPTLC methodology for the content of Levofloxacin in a medicinal dosage form was developed and validated by S. N. Meyyanathan et al. The reported method consists of silica gel GF 254 as supporting phase and composition of water, methanol, n-butanol and ammonia as eluent. The detection was done by using densitometer at 298nm.

Fen Yang et al. were investigated a methodology for the content of Cinacalcet HCl by using LCMS in human plasma. The analyte was eluted by preparing the eluent using mixture of ethyl nitrile, water and methanoic acid and the eluent flow of 0.3mL.min\(^{-1}\) on inertsil SIL-150 column and the column eluent was detected with the mass spectrometer. The reported ionization mode was positive electrospray ionization (ESI).

A trace level quantitative analytical method for Cinacalcet Hydrochloride present in human plasma by using HPLC was developed and validated on a HPLC column known as Mediterraneasea C18 column was published by I.A. Darwish et al. The published method prepared the eluent with the phosphate buffer and ethyl nitrile in a defined composition and adjusted the potential of hydrogen to 7.4. The proposed method was uniquely suitable for pharmacokinetic and bioequivalence studies of Cinacalcet Hydrochloride.

Amruta B. Loni et al. published a spectrophotometric analytical methodology for content of Cinacalcet HCl in API and solid medicinal unit. The published method was used two techniques for the
estimation of analyte by measuring the absorbance at 281nm. And also AUC(Area Under Curve) was calculated for a scale of wavelength i.e. 249-999nm.

K. Manikandan et al\textsuperscript{92} were done a HPLC methodology for the content of Cinacalcet HCl in bulk drugs. The authors used a eluent having composition of water and monohydroxymethane. The column eluent was detected at 271nm. The reported stationary phase was Phenomenax C18 column.

A spectrophotometric methodology for the content of Cinacalcet HCl in API was published by A. Manjula et al\textsuperscript{93} the analyte was determined by derivatisation of Cinacalcet moiety with 1,4naphthoquinonesulphonate in presence of tris buffer resulting into orange yellow colored chromogen of Cinacalcet. Thus obtained chromogen shows lambda maximum at 546nm.

Radhika Tekula et al\textsuperscript{94} validated a LC methodology for the estimation of Cinacalcet HCl in API and tablets. Cinacalcet was eluted by using composition of water, methanol and acetonitrile. The stationary phase is Inertsil ODS C18 column and 235nm as detection wavelength.

There was only one publication for the determination of Plerixafor by using HPLC and derivative spectroscopy in bulk drug reported by M.M. Annapurna et al\textsuperscript{121} The published method eluted the analyte using eluent by mixing the 10mM tetrabutylammonium hydrogen sulphate (pH-3.37) and ethyl nitrile with the eluent flow at 0.8mL.min\textsuperscript{-1} on C-18 column and the column outlet was detected at 215nm. And
also reported a derivative spectrophotometric method development by using the tetra butyl ammonium hydrogen sulphate buffer solution which shown a wavelength minimum at 226 nm.

Muralidharan S et al\textsuperscript{135} devoted a HPTLC methodology for the content of Dexibuprofen in its medicinally important formulations. The HPTLC methodology uses precoated silica gel 60 F254 plates as stable phase and eluent was having mixture of normal-hexane, acetoxyethane, ethanoic acid. The reported detection technique was by using densitometer in reflectance mode at the wavelength of 217nm.

P.G. Dhartarkar et al\textsuperscript{136} introduced a typical spectrophotometric methodology for the content of Dexibuprofen in API and its medicinally important forms. The analyte was dissolved in 5% methanol in pH 6.8 phosphate buffer and Dexibuprofen shown wavelength maximum of 221.8nm.

A TLC methodology for the Ibuprofen racemic mixture separation by using chiral mobile phase was reported by J. Krzek et al.\textsuperscript{138} The method proposed a stationary phase as aluminium Silica gel RP-18 F254 plates and mobile phase having mixture of $\beta$-cyklodextrin and methanol for the separation chiral compounds of Ibuprofen. The detection techniques used in this publication was densitometric detection at 222nm.

C. J. T. Thomas and S. Savage\textsuperscript{140} were reported a HPLC methodology for the content of Ibuprofen in API and medicinally important solid form. These researchers used eluent having mixture of
acetatebuffer and ethyl nitrile and the detection wavelength maximum was 254nm.

Y. Y. Lau reported a HPLC methodology for the content of enantiomers of ibuprofen in clear blood cells obtained from human beings by using fluorescence detector. The ibuprofen was extracted from the clear blood cells by using n-butyl chloride along with an internal standard (fenoprofen) and analysed with the eluent consisting a solution of acidic water and ethyl nitrile (33.5:66.5) on inertsil ODS-2 HPLC column and column eluent was detected by fluorescence detection at 280nm and 320nm.

H. Thomas Karnes et al have published a research program on typical technique of SPE (Solid-Phase-Extraction) and LC determination of Ibuprofen in clear blood cells. The SPE technique was automated using C2 extraction cartridge followed by HPLC analysis using eluent containing a mix of 20mM potassium phosphate solution and ethyl nitrile on Nucelosil C18 HPLC column. The column eluent was detected by using fluorescence detection technique at excitation wavelength and emission wavelength i.e. 253nm and 300nm respectively.

The content of Milnacipran in API and medicinally important formulation by UV spectrophotometric methodology was devoted by Punit P.B. et al. The Milnacipran was estimated by dissolving in distilled water and measured the absorbance at the wavelength of 220nm.
M Lecoeur-Lorin et al.\textsuperscript{153} research program revealed that enantiomeric excess of Milnacipran drug by using nonchiral HPLC equipped with circular dichroism detector. The publication was reported that the enantiomeric separation of Milnacipran can also be done by using non chiral stationary phase.

M. Srinivasa Rao et al.\textsuperscript{154} investigated RP-LC methodology for the content of Milnacipran in solid dosage units and method validation was performed. The reported method uses the eluent having mixture of pH4.8 potassium phosphate solution and methanol on waters ODS C-18 column. The wavelength maximum was about 210nm.