CHAPTER-2

Literature survey
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HPLC/UPLC is one of the versatile analytical techniques extensively used in the field of pharmaceutical and biological industries specifically for Qualitative and Quantitative estimation. Quantitative analysis plays an important role particularly in drugs and pharmaceuticals. In view of significance of chromatographic techniques in qualitative and quantitative analysis for significant therapeutic drugs and their formulations were identified for quantification and establishment of optimal procedures. Several investigators devoted for quantitative analysis and establishment of standard procedures for various kinds of drugs and pharmaceuticals dosage forms.\(^{26-37}\).

V Sirisha et al\(^ {38} \) had developed new analytical progress i.e. binary gradient reverse phase HPLC for the consideration of Rizatriptan benzoate in drug taster. In this method C18 Column with 5µ particle size, phosphate buffer of pH 2.5 and methanol in the proportion of 70:30 used as eluent. Elevated eluent flow rate is 0.8mL/min and detected at 227nm. The retention time was found 4.1min, recognition limit and limit of quantization were found as 0.96µg and 3.21 µg respectively.

Sachin S Jagtap et al\(^ {39} \) had invented stability representative by HPLC for the consideration of Rizatriptan benzoate in drug taster. In this method drug chromatographic separation from degradation products under stress conditions like oxidation, photolysis,
hydrolysis, and thermal decomposition was accomplished on a C18, column with 250 mm length 4.6 mm with 5 micron particle. In this method 0.01M sodium dihydrogen phosphate buffer and methanol (800:200 v/v) employed as eluent. The eluent flow was kept 1.0 mL/min and analysis scrutinised at 225 nm.

Palavai Sripal Reddy et al\textsuperscript{40} has invented dependable impurity relating technique and humiliation exploration for Sumatriptan succinate in combination of sumatriptan and naproxen saleable pills. The potential impurities were divorced on 250mm X 4.6mm, 5μm Spherisorb ODS-1 column by using gradient method with 0.05 M phosphate buffer pH adjusted to 3.0, methanol as well as Acetonitrile mixture as a mobile phase (500:250:250 v/v/v) and the eluent flow rate maintained at 1.0 mL/ min, impurities scrutinised at 225 nm.

A rapid, accurate and sensitive extractive spectrophotometric procedure was explore by B. Kalyana Ramu et al\textsuperscript{41} for quantification of sumatriptan succinate from drug substances and also developed a new Visible Spectrophotometric methodology For quantitative estimation of Sumatriptan Succinate Based on complex formation between nitrogen of the drug and acidic dye tropaelin (i.e Charge-Transfer )in the occurrence of 0.1M HCl through the maximum absorption at 482.5nm.

Simultaneous evaluation of Sumatriptan Succinate and Naproxen Sodium in drug material and in drug product by RP-HPLC Methodology was statement by Gondalia Riddhi et al\textsuperscript{42}. In this method C18 column (250x 4.6 mm, 5μ) was utilized, a mixture Acetonitrile:
Methanol: phosphate buffer at pH 6(50:10:40), was employed as a eluent and flow rate of eluent was kept 1.0mL/min and it was monitored at 229 nm.

Rajesh Kumar Nayak et al\textsuperscript{43}. made-up UV spectrophotometric technique for quantity of Sumatriptan in formulation dosage forms of pharmaceutical and bulk medication by spectrophotometer. Authentication testing were executed to reveal System suitability, Accuracy, Linearity, Specificity, ruggedness, Precision, robustness, detection and quantification limit. The method was established linear in the deliberation scope between 10-70 μg/mL. The method was initiated good recoveries (99.28- 100.37\%).

Tentu. Nageswar Rao et al\textsuperscript{44}. has predictable HPLC procedure for the strength of mind of Zolmitrptan in pharmaceutical dosage forms. In this method a kromasil C18 (150×4.6mm), 5μm column and eluent is a combination 7.5 pH phosphate buffer with methanol in the proportion of 75:25(v/v) was utilized respectively. Detection wave length was 230nm. The linearity was found satisfactory in the deliberation range of 2-0.01μg/mL and LOD, LOQ were established 0.01μg/mL and 0.03μg/mL of Zolmitriptan correspondingly.

D. Gowri Sankar et al\textsuperscript{45}. had created a simple, precise reverse phase approach for the strength of mind of Zolmitriptan in drug substances. The method was carried out employing a 150 mm × 4.6 mm with 5 μm particle, X-Terra RP C-18 column in an isocratic approach with eluent consisting phosphate buffer, methanol as well as acetonitrile into the proportion of 650:200:150 (v/v/v), a column
eluent flow was set for 1 mL/min. The eluent was inspect at 225 nm and the RT of the drug substance was established 4.27min.

Pragati Ranjan Satpathy et al⁴⁶ has developed & reliable a simple rational LC approach for zolmitriptan. Separation was performed by using a Symmetry C18 with 4.6 mm internal diameter, 150mm length of column, 5 µm, Make: Thermosil) and eluent was a mixture of aqueous buffer and methanol (35:65) and identified by using UV detector. The RT of zolmitriptan was found 2.460 ± 0.137min and Linearity was experiential in deliberation range of 30–70 µg/mL. The LOD and the quantification (LOQ) limit were found within limits and accuracy of the probable method was 99.4% for analyte.

R. Navaneeswari et al⁴⁷ developed and confirmed HPLC approach for Dutasteride and its impurities in bulk drug. This technique was acknowledged by make employ of the column of Zorbax Cyano 250 mm, 4.6 mm, with 5.0µm particles, the eluent was employed as Acetonitrile: phosphate buffer pH alter to 4.5 with dil. Ortho phosphoric acid solution (40:60v/v), the eluent flow rate of 1.2 mL/min at temperature 40°C were scrutinized at 210 nm for separation of impurities from the drug.

Md Ruhul Amin et al⁴⁸ developed simple, perfect and sensitive spectrophotometric technique planned for the fortitude of Dutasteride in raw material along with dosage form at the λ_max of 241 nm. The linear dynamic response was founded in the range of 12-28 µg/mL and coefficient of the correlation was originate to be 0.997. The %RSD value was lower than 2.0 indicated that the methodology was
extremely precise and LOD & LOQ were set up 0.125, 0.345 μg/mL respectively, which revealed that method was extremely sensitive.

HPLC technique was reputable for the assessment of Finasteride in drug ingredient by Manish Kumar Timmaraju et al. The division was accomplished by utilizing hypersil ODS C18 Column with 5μ particle size 250mm length, 4.6 mm, stable flow. Rheodyne injector with a 20 μl loop with a eluent composed in the proportion acetonitrile: KH₂PO₄ buffer (50:50 v/v), the eluent flow rate was reserved back 1.8 mL/min. The recognition was found at 208nm.

Simple, rapid determination of finasteride in human plasma by UPLC–MS/MS method was developed by Prasad B. Phapale et al. The plasma testers were arranged by abstraction with ethyl acetate, disappearance and reconstitution. The analysis were achieved on at triple–quadrupole and mass spectrometer by watching protonated parent→daughter ion pairs at m/z 373→305 for finasteride and m/z 237→194 for carbamazepine (internalstandard,IS). The methodology shows a direct reaction from 0.1 to 30ng/mL (r²>0.998). The quantitation limit (LOQ) for finasteride in plasma samples was 0.1ng/mL. Plasma analyte enclosing finasteride were constant underneath the three sets of circumstances verified and the administered analyte were constant up to 29 Hr in an auto sampler at 5°C.

An analytical HPLC technique for fortitude of finasteride in human plasma by liquid–liquid extraction method reported by P. Ptacek et al. The plasma samples were prepared with hexane–isoamylalcohol
(98:2, v/v). The mobile phase consists of potassium dihydrogenphosphate and acetonitrile–15mM (60:40 v/v) and detected at 210 nm.

Akheel A. Syed et al\textsuperscript{52}. developed a simple, rapid, reproducible and subtle, RP-HPLC for fortitude of finasteride (proscar) in preformulation, and it is used forced degradation studies. The method revealed admirable linearity \( (r^2 - 0.9997) \) in the assortment between 20-600 µg/ mL expenditure a Shimpak C8 column 150 mm, 4.6 mm i.d., with 5µm, and UV-detection at 210 nm at ambient situation(25°C) with a eluent of acetonitrile and water in the quantity of (95:5 v/v) and flow rate of eluent is 0.7 mL/ min.

K Basavaiah et al\textsuperscript{53}, an analytical HPLC approach established for determination of finasteride in tablets. In this method it was eluted from an ODSC18 column at ambient temperature (30 ± 2º C) with a eluent combination of water and methanol (20:80 v/v), the eluent flow was kept 1.0 mL /min, noticed at 225 nm. The retention time was \( \sim 6.1 \) min.

B. Mallikarjun Rao et al\textsuperscript{54} has developed and authenticated a stability representative HPLC technique for quantitative fortitude of Rizatriptan. In this method eluent was reached on Agilent Zorbax SB-CN (250mm×4.6 mm, 5 µm) column, eluent was a mixture of aqueous KH\(_2\)PO\(_4\) buffer (pH 3.4), methanol and acetonitrile.

E.K.S. Vijayakumar et al\textsuperscript{55} refined a new stability indicative of HPLC Methodology for assessment of Zolmitriptan. The related substances are known as impurity I and impurity II. In this method a
mixture of 0.02 M ammonium formate containing 0.1% \( n \)-propylamine plus acetonitrile in the quantity of 80:20 v/v utilized as a eluent. The chromatographic column Waters XTerra C18, 5 \( \mu \)m (250*4.6 mm), and column flow rate was held at 1.0 mL/min. The column thermostat was maintained at 33°C and the detection wavelength at 225 nm.

Niharika.V.L et al\(^56\). developed RP-HPLC modus operandi for the deliberation of Rizatriptan Benzoate in Oro-Dispersible Tablets. This method performed on Phenomenex Luna C18 (250mm×4.6 mm, 5\( \mu \)) column, amalgamation of pH 6.5 phosphate buffer, Acetonitrile and methanol (87:7.8:5.2 v/v/v) as the eluent and recognized at 225nm. Linearity was observed in 5-60 \( \mu \)g/mL of concentration and recovery standards were found 98.2-100.4%.

Chandramohan Nibe et al\(^57\). had advanced an Analytical Method (i.e. RP-HPLC) For fortitude of Rizatriptan Benzoate in Tablets. This method was mechanized with C18, 250 mm, 4.6 mm i.d., with 5 micron particle size, Aqueous buffer as well as Acetonitrile in the quantity of 90:10 v/v was employed as a eluent.

T. Joseph Sunder Raj et al\(^58\). had recognized for classification, categorisation and isolation of process-related impurities in Rizatriptan benzoate by LC–MS. Imp-3 [Rizatriptan-2, 5-dimer] was described in literature and erstwhile impurities were quarantined by developed method and categorised by using respective analytical methods.

Ravi Seshala et al\(^59\). a new, sensitive and specific isocratic RP-HPLC procedure with fluorescence detection has been developed and
confirmed for the detection of sumatriptan in rabbit plasma using sulpiride as an internal standard (IS). Chromatographic parting of the analyte and internal standard was accomplished on a Phenomenex C4 250mm × 4.6 mm i.d., with 5 µm), column maintained at 40°C. The eluent was composed of acetonitrile along with 25 mM ammonium acetate (pH 6.5) buffer (15:85, v/v) and the flow rate was reserved at 0.9 mL/min.

A simple LC technique for the quantitative fortitude of Dutasteride in drug materials and in formulation products was developed by D.V. Subbarao et al. The RT of Dutasteride was 7 min. When Dutasteride was imperilled to stress environments like oxidation, hydrolysis, thermal and photolysis degradation, degradation was found in hydrolysis and to a lesser extent under oxidation circumstances but the compound was stable to photolytic and thermal stress.

V Sreelakshmi et al. had refined and established a simple and rapid approach by RP-HPLC for simultaneous fortitude of Tamsulosin and Dutasteride in combined drug product. In this method Hypersil C18, 150 mm length, 4.6mm i.d., with 3.5 µm particles stationary phase employed with a eluent was a combination of aqueous phosphate buffer and Acetonitrile (30:70 v/v), buffer pH attuned to 3.5 with dil. orthophosphoric acid. The eluent flow rate was kept a 1.0 mL/min was executed at ambient temperature with a wavelength of 254 nm.

Development and validated a simple and sensitive RP-HPLC methodology for the concurrent assessment of Alfuzosin hydrochloride
and Dutasteride in bulk powder and dosage forms were reported by Shivprasad S. Deshmukh et al.\textsuperscript{62}. The RP-HPLC severance was executed on a HiQ Sil C18,HS column 250mm length,4.6 mm i.d., applying eluent methanol: water (90:10 v/v), the eluent flow rate was put 1.0 mL/min in room temperature. Quantitation by HPLC was accomplished at 244 nm.