REVIEW OF LITERATURE:

Literature survey is done on different analytical Method development and validation documents available in order to understand the work done till date, approach followed for development and validation. Following are few snapshots of literature reviewed.

1: **Pathare D. et all, (2006), Validated chiral liquid chromatographic method for the enantiomeric separation of Pramipexole dihydrochloride monohydrate.** A chiral liquid chromatographic method was developed for the enantiomeric resolution of Pramipexole dihydrochloride monohydrate, (S)-2-amino-4,5,6,7-tetra-hydro-6-(propylamino) benzothiazol edihydrochloride monohydrate, a dopamine agonist in bulk drugs. The enantiomers of Pramipexole dihydrochloride monohydrate were resolved on a Chiralpak AD (250mm×4.6 mm, 10_m) column using a mobile phase system containing n-hexane: ethanol: diethylamine (70:30:0.1, v/v/v). The resolution between the Enantiomers was found not less than eight. The presence of diethyl amine in the mobile phase has played an important role in enhancing chromatographic efficiency and resolution between the enantiomers. The developed method was extensively validated and proved to be robust.

2: **Pathare D. et all, 2007, A validated stability indicating LC method for Nateglinide.** The reverse phase high-performance liquid chromatography (RP-HPLC) method was developed for quantitative and related substance determination of Nateglinide is precise, accurate, rapid and specific. The method was completely validated showing satisfactory data for all the method validation parameters tested. The developed method can be used for the routine analysis and also to check the stability of Nateglinide.

3: **A.S Jadhav, et all, 2007, Development And Validation Of Enantioselective High Performance Liquid Chromatographic Method For Valacyclovir, An Antiviral Drug In Drug Substance.** A chiral high performance liquid chromatographic method was developed and validated for the enantiomeric resolution of Valacyclovir, l-valine2-[(2-amino-1,6-dihydro-6-oxo-9h-purin-9-yl) methoxy] ethyl ester, an antiviral agent in bulk drug substance. The enantiomers of Valacyclovir were resolved on a Chiralpak AD (250mm×4.6 mm, 10_m) column using a mobile phase system containing n-hexane: ethanol: diethylamine (30:70:0.1, v/v/v). The resolution between the enantiomers was found not less than four. The presence of diethylamine in the mobile phase has played an
important role in enhancing chromatographic efficiency and resolution between the enantiomers

4: Saidat.B and Baudah. F, et.all, 2010, High performance liquid chromatography chiral separation of D,L- Phenylalanine and D,L-Tryptophan with quaternary mobile phase mixture by copper mixed chelate complexation. A simple and rapid HPLC enantio separation of D, L- Phenylalanine and D, L-Tryptophan was developed.


8: Maniknandan.K and Karunanidhi.S, et.all, 2013, Stability indicating HPLC method for the Estimation of Cinacalcet hydrochloride API. A stability indicating liquid chromatography method has been developed and validated for the determination of cinacalcet hydrochloride in a laboratory mixture as well as tablet formulation developed in house. The proposed method is simple, accurate and rapid.


10: Mondal.P and Neeraja.B, 2013, Development of new simple and economic validated RP-HPLC method for the determination of famciclovir in bulk and tablets dosage. A simple sensitive and isocratic RP HPLC method was developed for
the determination of Famciclovir in bulk and tablet dosage form. The proposed method was found to be a simple, economic, fast, accurate and precise.


15: Hemsagar Jadhav and Dnyandeo Pathare, 2015, Enantiomeric Separation of Etodolac in A Bulk Drug Substance by Reverse-Phase Chiral Liquid Chromatography Method. A novel, simple and rapid enantiomeric separation of Etodolac by reverse-phase high-performance liquid chromatographic method as per ICH guidelines. CHIRAL-AGP, (100 x 4.0 mm i. d, 5µm) column using a mobile phase
system containing 0.1 M sodium dihydrogen phosphate dihydrate pH 4.0 buffer: Isopropanol (85:15 v/v.) at detector wavelength 225 nm and column temperature 25 °C. The chromatographic resolutions between R-isomer and S-isomer were found three.

16: Hemsagar Jadhav, 2015, Determination Of R- Isomer Impurity Of Pantoprazole Sodium In A Bulk Drug Substance By Normal Phase Chiral Liquid Chromatography Method. A novel, simple and rapid R- isomer impurity determination of Pantoprazole sodium by normal-phase high-performance liquid chromatographic method as per ICH guidelines. Chiralpak AD-H, (250 x 4.0 mm i. d, 5 µm) column using a mobile phase system containing n-Hexane: Ethanol: Trifluoroacetic acid (80:20:0.1 v/v/v.) at detector wavelength 290 nm and column temperature 20 °C. The chromatographic resolutions between R-isomer and S-isomer were found three.

17: Hemsagar P. Jadhav, Dnyandeo B. Pathare, 2015, Separation and Determination of the S-Isomer of (10-Camphorsulfonyl) Oxaziridine in A Bulk Drug Substance by Normal-Phase Liquid Chromatography. A novel, simple and accurate enantiomeric separation of (10-Camphorsulfonyl) oxaziridine by normal-phase high-performance liquid chromatographic method as per ICH guidelines. Chiralcel OD-H (250 x 4.0 mm i. d, 5 µm) column using a mobile phase system containing n-Hexane: ethanol: trifluoroacetic acid (90:10:0.1 v/v/v.) at detector wavelength 210 nm and column temperature 30 °C. The chromatographic resolutions between S-isomer and R-isomer were found three.