LITERATURE REVIEW:

Various methods for analysis of API in Pharmaceutical drug or API as such are used now a day. But more popular methods are

- High Performance Liquid Chromatography
- UV-VIS Spectrophotometry
- Thin layer Chromatography

Many methods have been developed and validated for API and estimation of API in their formulation form, Using HPLC, UPLC, UV etc.

Validation of a HPLC or UV method has been carried out as per ICH guideline or US Pharmacopeia Guideline.

The new HPLC method for estimation of levetiracetam in its tablet dosage form has been developed. Mobile phase consist of buffer solution (pH=2.8) and acetonitrile in the ratio of 90:10. Prontosil C18 column was used to achieve separation. The flow was set at a rate of 1.2 mL/min and UV detection at 215 nm. The percentage recovery of levetiracetam was found to be 99.08%. This condition is applied for tablet dosage form only.¹

RP-HPLC method for determination of riluzole hydrochloride in bulk and tablet dosage forms was developed by SreekanthNama, Bahulal Z. Awen, BaburaoChandu and MikkantiKagga. They developed this method on hypersil ODS analytical column. They used 5M ammonium acetate and acetonitrile in the ratio of (1:1) v/v as mobile phase. The flow rate set as 1.0 mL/min. Detection was made on PDA detector at 220 nm wavelength. The developed and validated method can be applied for the quantitative analysis of Rilutek tablets. This method is simple, specific, rapid, reliable and reproducible. This method also describes recovery study.²

Gopalkrishanan S.,Vadivel E.,Krishnaveni P., and B.Jeyashree developed the RP-HPLC method for Mycophenolate Sodium drug and validated this method, using USP L7 octyilsilane chemically bonded to porous silica C8 column. Mixture of acetonitrile and buffer (0.1% orthophosphoric acid) was used in the ratio of (50:50). The flow rate was set at 1.5 mL/min.
nm wavelength was chosen in PDA detector for measurement. This method shows good linearity and less %RSD.\textsuperscript{11}

A method for the simultaneous estimation of Glibenclamide and Metformin HCl in Bulk and Tablets using UV – visible spectroscopy was developed and validated. This method reveals a spectrophotometric method for the simultaneous estimation of glibenclamide and metformin hydrochloride in combined dosage form using methanol as a solvent, the two wavelengths 229.5 nm and 237 nm were selected for estimation of glibenclamide and metformin HCl respectively. The method was validated successfully as per ICH guidelines, the method can be employed for estimation of pharmaceutical formulations with no interference from any other excipients and diluents.\textsuperscript{21}

Method development and validation of determination of Amoxicillin in pharmaceutical dosage form and bulk drug by RP-HPLC was carried out by Manzoor Ahmed, Suresh Babu G. Satish Kumar Shetty A. Here the RP column used was a Hypersil C18 column. The mobile phase was mixture of potassium dihydrogen phosphate with a flow rate of 1.0 ml/min. Limit of Detection and Limit of Quantification was also determined.\textsuperscript{16}

Rajia Sultana Nijhu and coworker Developed UV spectrophotometric method for Quantitative estimation of nitroglycerin in its dosage form. Nitroglycerin shows UV absorbance maxima at 210 nm. Concentration range was 15 µg/mL in methanol. The developed method was successfully validated with parameters like System suitability, method precision, accuracy, specificity, linearity and robustness and proven to be rugged.\textsuperscript{23}

Uma Devi S., PushpaLatha E., NagendrakumarGupta C.V., and Ramalingam P. have developed method of HPTLC for estimation of ziprasidone hydrochloride in bulk and pharmaceutical dosage forms. Aluminium plates coated with silica gel F\textsubscript{254}as stationary phase was used. 1-Butanol : Dimethyl Sulfoxide : GAA (8.1 : 1.2 : 0.7 v/v/v) taken as mobile phase. Densitometric evaluation of the separated bands was performed at 254 nm using camag TLC Scanner-3 with win CAT 1.4.4 software. Also the validation was carried out statistically and recovery studies. The method was validated according to ICH guideline.\textsuperscript{28}