ABSTRACT

The current dissertation research work mostly emphases on the stability indicating newfangled analytical method development by means of present liquid chromatographic techniques of HPLC and UPLC to expedite the quality control check of medicinally important components as such and its pharmaceutical dosage forms in this pharmaceutical era. This research program breakdowns the impede in thirst for necessity in effortless, defined, perfect and isocratic reverse phase liquid chromatography techniques. One firmly states that no one single active pharmaceutical ingredients industry can produce or synthesize a hundred percent pure medicinally important organic compound. The therapeutic activity of a medicinally important organic compound is completely dependent on its purity. If the medicinally important compound is not pure enough it results major side effects to the human beings who are getting treated with the respective medicinally important compound. Consequently, to define the purity of a medicinally important compound will lead as requisite for new analytical techniques.

The present research study confronts five selective medicinally important organic compounds with diverse therapeutic activity in pharmaceutical domain. Those drugs are Levofloxacin, Cinacalcet Hydrochloride, Plerixafor, Dexibuprofen and Milnacipran Hydrochloride. The designated medicinally important compounds selectively chosen based on the pharmacological activity of the respective compounds. And the selected compounds pharmacological
category was defined as, Levofloxacin is a third generation fluoroquinolone Antibiotic, Cinacalcet Hydrochloride acts as calcimimetic, Plerixafor acts as Anti-Cancer drug, Dexibuprofen is a NSAID and Milnacipran Hydrochloride acts as Anti-Epileptic.

Literature survey on five chosen medicinally important organic compounds was done extensively. It revealed that there were no methods reported for two medicinal compounds namely Cinacalcet Hydrochloride and Plerixafor and few methods were reported for the rest of three medicinal compounds namely Levofloxacin, Dexibuprofen and Milnacipran hydrochloride. Nonetheless those reported methods were shown less separation between impurities and with the main peak, and are troublesome gradient methods, lower analytical techniques, tedious procedures, different and difficult detection techniques and were not meeting the current regulatory requirements.

An analytical method once it has been developed, it has to be deep-rooted through various steps to prove that the developed methodology is valid to use. So, the analytical methods developed in the current research program were proven to be valid in accordance to International Conference on Harmonization (ICH) guidelines for use in regular quality check of the medicinally important drug substances. The newfangled analytical methods were developed and validated by keeping in view on current regulatory requirements and as per ICH guidelines. Consequently the reported analytical methods in the current research program are useful for the purity quantification of the respective medicinal compounds in as such form as well as
pharmaceutical dosage forms especially in pharmaceutical research and development centers, regular quality testing laboratories of pharmaceutical industry, novel research programs such as new drug delivery systems, abbreviated new drug delivery and novel drug delivery systems etc.