NEED FOR STUDY

Analytical study plays a role of paramount importance as new ventures in the area of medicinal chemistry is a continual affair. New drugs are introduced in the market from time to time. Similarly, a huge number of biological products and vaccines are entering into the new drug market.

It is necessary in this context to relook into the older methods and further search for new methods to decide on the efficacy, cost and selectivity of the method. It is imperative therefore, to develop analytical methods based on the main dictum which have simple, precise, accurate and reproducible results.

The present work mainly focuses on the analytical method development studies from the existing U.V. spectroscopic, HPLC, LCMS and HPTLC methods. The study has been extended to the area of polymorphs through DSC, IR, TGA, NMR, SEM. PXRD, single X-ray crystallography and synthesis of salt/co-crystal.

For this purpose, spectrophotometric method for the estimation of sitagliptin phosphate in bulk and tablet has been undertaken. Literature survey has revealed that only LCMS method has been reported and so far no UV derivative spectrophotometric studies are available. As spectrophotometric studies are popular on the basis of their simplicity, specificity and low cost, the present study is undertaken to develop a new spectrophotometric method for sitagliptin phosphate.

This study is further extended to develop a reverse phase, gradient LCMS method for sitagliptin phosphate, so as to get a sensitive, precise and accurate method for the determination of sitagliptin phosphate in human plasma. This method can be used for clinical trial and pharmacokinetic study.

As HPTLC methods have come into general use, they cannot be ignored. The present work is further extended for the estimation of cefuroxime axetil in bulk and
pharmaceutical formulations. The method is validated for accuracy, linearity and precision by following the ICH guidelines.

The future lies in the studies on polymorphism of drugs. Many drug candidates exist as polymorphs and their solubility studies indicates the differences in their efficacy. It is also noted that when the drug is stored, there may be a change in the structure of polymorphs. Hence, X-ray crystallographic study has become indispensable. The X-ray crystallographic studies follow after identifying the polymorphism through the differential scanning calorimeter and their proportions through differential thermogravimetric analysis. The different polymorphs are subsequently identified through IR and NMR studies. A solid state NMR study cannot be overruled to identify and quantify correctly the polymorph.

Time and again it has become necessary to obtain the drug as salt / co-crystal. The introduction of the drugs as salt /co-crystal is essential for solubilization, palatability and patient acceptability. Only a few, to name, piperazine citrate, chloramphenicol maleate, erythromycin estolate are available in the market. The salt /co-crystal study and synthesis have been therefore an accepted concept and will have more dynamic importance in the future development of drugs and also on development of analytical methods.

Polymorphism study for the reasons stated earlier, was undertaken for cefuroxime axetil and cefadroxil monohydrate using different analytical instruments.

As stated earlier, on the importance of synthesis of salt formation, a new process for crystallization for the drug used in respiratory disorders, bromhexine, was taken by using p-toluene sulfonic acid as organic solvent for the first time and was evaluated by single crystal X-ray crystallography.
The drugs in the present study are selected on the basis of their availability and also on account of not much work being reported on these. Therefore as many analytical methods as possible are being tried on these type of drugs.