ABSTRACT

The proposed research work mainly focus on the development of stability indicating new Analytical methods by using modern chromatographic techniques like HPLC and UPLC to check the quality of active pharmaceutical ingredients (API’s) in pharmaceutical sector. The proposed work also includes the analytical method validation of the newly developed methods as per International Conference on Harmonisation (ICH) requirements and also to assess the stability of active pharmaceutical ingredient during stability studies. The development of a suitable validated stability-indicating analytical methods are very important for pharmaceutical industry to perform the quality testing of the pharmaceutical bulk drugs development. As per the current ICH and regulatory requirements the evaluation of stability samples must be carried out using stability-indicating analytical methods. A review of literature reveals a large number of methods reported over a period of 3 - 4 decades for quality testing of the drugs. However, most of the reported methods are having higher run time, less separation of impurities from main peak and fall short in meeting the current regulatory requirements. To meet the regulatory requirements the methods should be specifically validated and the method must be stability indicating.

Five different classes of active pharmaceutical ingredients (API’s) namely Zolmitriptan, Rizatriptan benzoate, Sumatriptan succinate,
Finasteride and Dutasteride bulk drugs were selected for present research work keeping an objective to develop suitable validated stability-indicating analytical methods for their quality monitoring and assessment. Literature search reveals that no stability-indicating UPLC/HPLC analytical methods for selected API’s were reported as on date. Suitable novel stability-indicating HPLC/UPLC methods were developed by keeping in views of the current regulatory requirements in mind and the developed methods were comprehensively validated. The performance of the developed UPLC methods has been verified by applying the same to evaluate the quality of bulk samples of API during its production as well as during their stability studies. The developed UPLC methods were performed well for the quality evaluation of stability samples of API’s. Validated novel stability-indicating UPLC/ HPLC methods were developed for five active pharmaceutical ingredients (API) namely Zolmitriptan, Rizatriptan benzoate, Sumatriptan succinate, Finasteride and Dutasteride. The optimised methods were very much useful for the quality assurance of the drugs during their manufacturing as well as during their stability studies in pharmaceutical industry prior to the release of bulk samples for using in the preparation of drug products which are release in the market. All the methods were fully validated as per the ICH and regulatory requirements. They were also very useful to evaluate the quality of active pharmaceutical ingredients (API’s) during its stability, which helps to provide the correct retest and expiry date.