

ABSTRACT

Pharmaceutical drug products play a vital role in human progress by finding curing for diseases. Today, a majority of the drugs used are of synthetic origin. They are produced in bulk and used for their therapeutic effects in pharmaceutical formulations. There are biologically active chemical substances generally formulated into convenient dosage forms such as tablets, capsules, suspensions, ointments and injectables. These formulations deliver the drug substances in a stable, non-toxic and acceptable form, ensuring its bio-availability and therapeutic activity.

The end user of the drug product has to be assured of the medicine's quality, which makes suitable testing of the materials an area of great concern. Thus, the analytical activities concerning purities in drug products are among the most important issues in modern pharmaceutical analysis.

This subject or topic for this research activity is selected based on the increasing need for the pharmaceutical industry to develop suitable analytical methods. Among various other available techniques, the scope of work was focused on the modern chromatographic techniques such as HPLC and UPLC, which are very powerful and sophisticated techniques and have a wide spectrum of applications in the pharmaceutical industry. The development and validation of such a chromatographic method needs a lot of theoretical study, practical knowledge, skills, capability of application, literature search and visualisation of experimental and extrapolated results and assessment of the right conditions for use and method application and finalization. Some products were reviewed, and it was felt that there is a need to develop new, simple and reliable analytical methods.

Five chromatographic methods were developed for different pharmaceutical drug products. The first method was developed for the estimation of Sofosbuvir and Daclatasvir. The second method was developed for the estimation of Ombitasvir, paritaprevir, ritonavir. The third method was developed for the estimation of

Abacavir, Dolutegravir, and Lamivudine. The fourth method was developed for the estimation of Bictgraviremtroicabine, tenofovirafenamide.

The developed methods were validated according to the ICH (International Conference on Harmonization) guidelines and proved suitable for quality control of the drugs in pharmaceutical preparations.