ABSTRACT
The research work is mainly concerned with impurities and other related substances present in the formulation as impurities are identified and method is developed. The method is validated according to ICH (International council of harmonization) for linearity, range, accuracy (correctness), precision (reproducibility), limit of detection (LOD), limit of quantification (LOQ), robustness, ruggedness, repeatability, stability, system suitability. The stability factors are checked in acidic medium, alkaline medium, at different pH range, at different temperatures. There are number of preparations that have many similar or degraded impurities during preparations and these are not being separated properly. In this research Anstrazole, Rupatadine and Rifapentine drugs are used and method is developed on HPLC or high pressure liquid chromatography. The impurities are identified as impurity A, impurity B, Impurity E etc. and method is developed in the presence of impurities. The amounts of these impurities are negligible and cannot affect the preparations for their therapeutic actions. If, impurities in large amount may be harmful to the mankind and those should be removed from the preparations.