OBJECTIVE:

Based on literature survey, it was revealed that, although the chromatographic work has been done on a single drug, there is no any HPLC method for combination of drug in tablet dosage form. Hence it was felt that there is a need to develop a new analytical method for the estimation of Trandolapril and Verapamil HCl by RP-HPLC method. The objective of present work is to develop HPLC method for a combination of drug in tablet formulation and also to perform the stability study of the same formulation along with the validation of analytical method.

As per the stability test guidelines Q1A issued by ICH, analytical test procedures for stability samples should be fully validated and the assays should be stability-indicating. Aiming this guideline, the present work will be as per the recommendations of ICH. Intrinsic stability of the drug will be established by exposing both the drugs to different stress conditions and finally developing the validated stability-indicating HPLC assay for the formulation containing both the drugs. The method should be used to determine the purity of drugs available from various sources by detecting any related impurities. Because the method could effectively separate the drugs from their degradation products, it can be regarded as stability indicating.

HPLC methods are more accurate and sensitive and hence now days are of first choice for the workers than that of UV methods. Even Pharmacopeias also replacing the chemical and Spectrophotometric methods by more sensitive and accurate HPLC methods for the analysis of drugs. Hence development and validation HPLC method for analysis of formulation is the prime objective of present work.

Developed method will be validated using the various validation parameters as per ICH guidelines. The extent of degradation as well as the interference from various degradants that will produce after degradation will be studied using force degradation. This method will also be validated to confirm its reliability and reproducibility. The Method will be developed to give accurate, precise and reproducible result, hence the quantification of the drug product will be accurately performed and hence the HPLC is the first choice for analytical investigation.