2. AIM AND OBJECTIVE

The drug analysis plays a vital role in the drug development, manufacture and therapeutic use. Pharmaceutical industries relay up on quantitative chemical analysis to ensure that the raw material used and the final product obtained meets the required specifications. The number of drugs and drug formulations introduce into the market has been increasing at an alarming rate. These drugs or formulation may be either new entities in the market or partial structural modification of the existing drugs or novel dosage form or multi dosage forms.

Various regulatory authorities like ICH, Canadian drug and Health agency are emphasizing on the purity requirements and identification of impurities in API. Qualification of the impurities is the process of acquiring and evaluating data that establishes biological safety of an individual impurity thus, revealing the need and scope of impurity profiling of drugs in pharmaceutical research.

In the last decade a considerable effort has been made both by the regulators and the pharmaceutical industry to assess Geno Toxic Impurities (GTI) in pharmaceutical products. Though the control of impurities in drug substances and products is a well-established and consolidated procedure, its extension to GTI has given rise to a number of problems, both in terms of setting the limits and detecting these impurities in pharmaceutical products.

The three drugs candidates of Phenytoin (PHY), Warfarin (WAR) and Nicergoline (NIC) were selected based on the its usage. All the three drugs were prescribed by the physician to the patients from childhood to adult stage. The Benzil (BZL), Benzalacetone (BAZ) and 5-Bromo Nicotinic Acid (5BNA) impurities (IM’s) were raised in PHY, WAR and NIC as a reactant impurity respectively. Even though the IM’s are acceptable to present as per monograph. These impurities were reported for toxic positive controls\textsuperscript{58,59}. The present study aims to develop simple accurate, precise and sensitive method to estimate the amount of IM present in the selected bulk drugs and
pharmaceutical dosage forms. The IM’s present in the PHY, WAR and NIC drug were further screened for its GT effect by AMES Test and Nicking assay to prove its biosafety.