**Editorial**                                                                          **Open Access**

# An Overview of Pharmaceutical Impurities and Degradation Products

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## Structure of the Editorial

Quality, purity, safety and efficacy of pharmaceuticals are the fundamental issues of importance in drug therapy. A greater emphasis is being paid today on assurance of the quality and safety of a drug by monitoring and controlling the impurities and degradation products. The control of pharmaceutical impurities, unwanted substances is a critical issue for the pharmaceutical industry since their presence in the active pharmaceutical constituents and its dosage forms diminish both drug quality and safety. By the identification or characterization and quantification of the impurities and related substances, the risk of their contribution to the side effect profile of the drug therapy can be avoided or minimized. Moreover, the characterization of such trace to minor analytes in the final product is the inherent prerequisites in the wake of stringent requirements from the regulatory authorities. Hence, the development of new analytical methods became an essential task for investigators to determine the stress-related impurities along with their degradation pathway. A forced degradation study (stress testing) is the main tool used to predict stability problems, develop analytical methods, and identify degradation products or pathways. Since, the subject of stress testing has insufficiently addressed in the scientific literature, the measurement, and identification of impurities by today's standards present significant challenges to the analytical chemist. The development of modern quantitative and qualitative methods driven by these challenges has provided increasing opportunity to detect, identify, and quantify organic and inorganic impurities in bulk drugs and pharmaceutical formulations, and therefore, the origin and safety potential, of such impurities. Recent efforts by the International Conference on Harmonization (ICH) have led to greater regulative scrutiny of impurities, constraining their isolation, characterization and toxicological qualification when present at threshold levels. Moreover, the toxicological profiles of the active drug substance as well as the adverse effects of the related impurities govern the safety of a drug product. It is important to determine the cytotoxic, genotoxic and mutagenic activity of impurities thereby establishing their structure-toxicity relationship using various assay procedures. Worldwide, characterization or impurity profiling of drug substances has increasingly viewed as a precious complement to routine investigative work, adding valuable, scientific information in support of their vulnerability to stress conditions and degradation pathways. Impurity profiling has definite techno-commercial value since the pharmaceutical industry is facing the challenge of impurities that diminish the quality, safety and efficacy of drug substances. Due to lack of adequate scientific literature, it is necessary to incorporate stringent tests to control the impurities like by-products, transformation products, degradation products, interaction products, and related products, residual solvents and impurities relating to the inert ingredients (excipients). This fact is also evident from the requirements of the Federal Food, Drug and Cosmetic Act and from a large number of pharmacopeias that provide tests for the control of specific impurities. Forced degradation and impurity profiling is one of the key prerequisites for investigational new drug (IND) and new drug application (NDA) registration. Hence, the estimation of impurity profiles of bulk drug substances is a frequent task, especially in industrial analytical research and quality control laboratories. The significance of impurity profiling has well reflected by the fact that in the recent years numerous books, book chapters, review papers and innumerable ordinary papers have been published on this subject dealing with HPLC, HPTLC, UPLC, LC-MS/MS and many more aspects to emphasize impurity profiling as a hot topic in contemporary pharmaceutical analysis. Impurity profiling study henceforth may be highly supportive for process development, quality assurance as well as routine analysis of commercial formulations. Stress testing and stability indicating analytical procedures provide data to support the characterization of potential degradants; degradation pathways and intrinsic stability of the drug molecule. Unanimously, combinations of chromatographic and spectroscopic techniques have been proved as valuable tools for forced degradation and estimation of impurity profiles in drugs and related materials. Fortunately, the revolutionary advent of a variety of sophisticated hyphenated techniques with liquid chromatography has made this much simpler than the traditional time-consuming approach of quantification, isolation, followed by acquisition of the spectral (mass, UV, NMR and IR) and elemental (C, H, N) data.

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