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Toxicological assessment of degradation products: Is it relevant as a complementary approach during stability testing of pharmaceuticals?

Daniele Rubert Nogueira
Federal University of Santa Maria, Brazil

Drug stability means the ability of the pharmaceutical dosage form to maintain its physical, chemical, therapeutic, microbial and toxicological properties during the time of storage and usage by the patient. Stability testing of pharmaceuticals measures the rate of changes that take place in the pharmaceutical dosage forms, which can support its formulation and packaging. For this purpose, a stability-indicating analytical method is necessary to quantitatively determine the presence of degradation products, and also to measureactive ingredients free from any interference. The first step to develop a stability-indicating analytical method is the generation of degraded samples for testing its selectivity. Later, it is recommended the isolation and identification of degradation products by using complementary analytical tools such as mass spectrometry and RMN.Finally, the performance of toxicological studies of degraded forms is gaining growing attention and seen to benecessary. The need for identification and qualification of degradation products follows defined thresholds and should be based on scientific rationale and toxicology level of concern. The *in vitro* cell-based cytotoxicity assays are potential approaches to be applied especially in preliminary toxicological studies, due to their high-throughput performance, and important advantages over *in vivo* methods respect to ethical aspects and expenses of animal testing. Even if the level of degradation products is lower than the threshold, the performance of safety testing should be considered. When a potential toxic product is generated, it can be harmful to human health even at very low amounts. In line with the overall safety concerns of pharmaceuticals, a complete stability profile of a drug product needs to be established to assure its safety, efficacy and quality.

Biography

Daniele Rubert Nogueira has completed her Master degree in 2007 in Drug Quality Controlfrom Federal University of Santa Maria (Brazil). Recently,she finished her PhD from University of Barcelona (Spain) in the field of toxicology. She has held a professor position at Federal University of Santa Maria, and now is postdoctoral researcher at this same Institution. She works in the fields of analytical method validation, drug quality control and in vitro toxicology. She has published more than 25 papers in reputed journals.

daniele.rubert@gmail.com