Impurities in pharmaceutical products do not offer any therapeutic benefit for the patient and sometimes may be potentially toxic. Impurity level is a critical quality attribute for a drug substance or a drug product. Control of impurities in drug substance and drug product is described in ICH Q3A, Q3B and Q3C. Impurities in pharmaceutical products do not offer any therapeutic benefit for the patient and sometimes are potentially toxic. Impurity level is a critical quality attribute for a drug substance or a drug product.

An overall impurity control strategy was developed to achieve the desired quality of the drug substance/product. Control strategy is designed via material quality control and process control steps and ultimately by drug substance/product.

Defining Control Strategy (CS)

A control strategy for impurities may include, but is not limited to, the following:

- Identification of unit operations that would be involved in the manufacturing process
- Identification of impurities (CQAs) that can be formed during the manufacturing process

These are the controls which are put into place in order to monitor and adjust the process as and when required to ensure that API or its intermediates conforms to its specifications thereby ensuring that API or its intermediates conforms to its specifications.

Traditional Vs. Enhanced approaches for Pharmaceutical Development

Various Approaches to CS for Impurities

Comprehensive Approaches for Developing Overall Control Strategies for Impurities in Drug Substances and Drug Products

Bharathi Mamidipudi, Hiral Gutka, Prabu Nambiar

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Methods

Instead of controlling the impurities by adding the impurities at the end, the CS paradigm allows strategic and science-based approaches to control impurities at various stages. Control points such as in-coming material controls (for excipients), process controls (for intermediates) and product testing are different for various reasons. Based on the knowledge of the type of impurities and their potential sources, a comprehensive control strategy is designed via material quality control and process control steps and ultimately by drug substance/product specifications.