Multiproduct Cleaning Validation: Acceptance Limits for the Carryover of Inactivated API Part I–The Comparable Quality Approach

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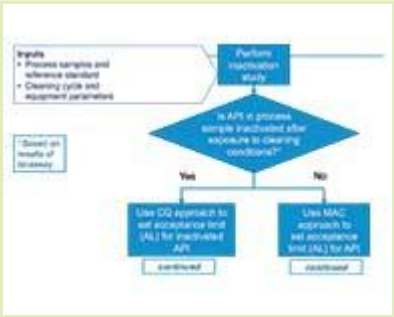

A methodology for evaluating the degree of inactivation of a product during cleaning and setting acceptance limits for the carryover of inactivated product in multiproduct equipment is described. A new approach for justifying acceptance limits for inactivated product, known as the comparable quality (CQ) approach, is described in Part I; the application of this approach to biopharmaceutical cleaning will be described in Part II. The general principles of the CQ approach are applicable to most active pharmaceutical ingredients (APIs). Download "Multiproduct Cleaning Validation: Acceptance...