

WHITEPAPER

STABILITY STUDIES ACROSS THE DRUG PRODUCT LIFECYCLE

Abstract

Stability studies play a fundamental role across the lifecycle of pharmaceutical products to demonstrate that a new drug substance or drug product is within acceptable chemical and physical limits.

A host of considerations must be incorporated into the study design at the outset, with many variables that depend on the product type, the development phase, and the region that the product will be marketed in. In this paper, Tasmina Bokhari, Stability Team Leader, provides a review of the role stability studies play across the product development process.

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