BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING

Overview

Bracketing is a strategic approach used in pharmaceutical development and stability testing to reduce the number of samples while maintaining data integrity. It involves testing only the extremes—such as the highest and lowest strengths or the largest and smallest container sizes—based on the assumption that the stability of intermediate configurations is represented by these bounds. This approach is especially valuable when dealing with multiple strengths, container types, or package sizes, offering efficiency without compromising scientific rigor.

ICH guideline Q1D, *"Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products*," provides regulatory support for this strategy. It outlines when bracketing is appropriate, stressing the importance of prior knowledge and risk assessment to ensure untested configurations are adequately covered. ICH Q1D encourages bracketing to optimize resources and reduce testing burden, as long as it is scientifically justified and aligned with the known behavior and characteristics of the drug product. Suppliers can apply bracketing when transitioning to a different pack size, or container closure system.

Link to Guidelines

ICH OFFICIAL WEBSITE : ICH QUALITY GUIDELINES Q1D-BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS