A GENERAL TECHNIQUE FOR SETTING SPECIFICATION LIMITS IN STABILITY STUDIES

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Stability studies are conducted to establish or confirm the shelf life of a pharmaceutical product. The shelf life is defined as that time for which the estimated responses for specific limiting characteristics of the product exceed predefined specification limits. Depending on the pharmaceutical product, confidence or prediction intervals are constructed about the estimated limiting characteristic response to accommodate future batch response. Tolerance intervals are often used to help support the setting of specification limits when confidence intervals are to be used to estimate shelf life. However, when prediction intervals are to be used to determine shelf life, there is no well-accepted statistical methodology to support the setting of specification limits. Previous research has extended the concept of tolerance intervals to prediction intervals. An example is presented detailing how the proposed tolerance intervals are used to support setting specification limits for stability studies.