Validation of Dissolution Methods

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Validation of analytical methods in the pharmaceutical industry is a well-known requirement of current good manufacturing practices, and dissolution methods fall under this requirement. The validation exercise for dissolution methods addresses key areas including product performance reproducibility, solutions stability, and detection of changes in formulation, process, and product performance on stability. The approach to method validation must be based on good science and a defined strategy. This includes identification of the analytical target profile and associated modern expectations for...