

## General Considerations for Dissolution Methods: Development, Validation, and Transfer

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### KEY POINTS

The following key points are discussed:

- The dissolution method is important because it is the only test that addresses product performance.
- Dissolution methods may be used for different purposes, and the method development process should address these specific goals.
- The validity of the dissolution test must be demonstrated. This is generally accomplished by examining the ruggedness of the method and conducting a series of validation experiments.
- Because the implications of a failing dissolution result can be huge, it is important to have a rugged method with appropriate discriminating power.
- Changes encountered during the product lifecycle may present challenges to the ongoing validity of the method. These include changes to both the drug product and the testing laboratory.

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