

Accelerated Degradation of Pharmaceuticals and Related Chemical Processes

A rapid forced degradation method using Leidenfrost droplets and nanospray mass spectrometry dramatically cuts stability testing time from days to minutes, streamlining drug development and FDA licensing.

Forced degradation is an accelerated method of studying the stability of an active pharmaceutical ingredient (API) in order to predict the shelf life of the drug. Forced degradation studies of APIs are an important aspect of pharmaceutical development. Typical forced degradation methods take one to seven days to complete and are then followed with product analysis using liquid chromatography-mass spectrometry (LC-MS). These methods are time consuming and costly. There is a need for a more efficient method of forced degradation.

Researchers at Purdue University have developed a new forced degradation method. Using Leidenfrost droplets to accelerate forced degradation and nanospray mass spectrometry (MS) to characterize the reaction products, the reaction/analysis sequence provided results within minutes, i.e., five minutes, versus taking up to a week to complete. The FDA requires forced degradation for licensing, which causes a bottleneck in pharmaceutical production. An accelerated forced degradation method could help eliminate this bottleneck.

Advantages:

- Faster
- More efficient
- Reliable
- Potential to speed up FDA licensing process

Potential Applications:

- Pharmaceutical industry

Technology ID

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Category

Pharmaceuticals/Drug Discovery
& Development
Biotechnology & Life
Sciences/Analytical & Diagnostic
Instrumentation

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-Drug development

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