財団 Information ▶報告書

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溶出試験におけるマウント回避を目的としたApexベッセルの有用性に関する検討*2

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Study on the Usefulness of Apex Vessels for Avoiding Mounting Issues in Dissolution Testing*2

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Summary

This study investigated the utility of Apex vessels to prevent "coning" in dissolution testing, a phenomenon where the test formulation accumulates under the paddle, leading to unexpectedly slow dissolution profiles. Two Apex vessels commercially available in Japan were evaluated, focusing on their geometrical features and the dissolution behavior of different drug formulations in them. The study found that Apex vessels effectively mitigated coning in certain cases, with significant improvements noted for formulations such as levofloxacin fine granules. However, differences in dissolution were observed between the two vessels for atorvastatin calcium hydrate tablets, highlighting the need for further hydrodynamic analyses. The findings suggest that while Apex vessels show promise for addressing coning issues, careful case-by-case assessment will be essential for their adoption in regulatory and industrial settings.

Key words

Dissolution test, Apex vessels, Mount