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Classification of Drug Permeability with a Caco-2 Cell Monolayer Assay

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Abstract

In the absence of an optimized and validated protocol for the Caco-2 cell drug permeability assay, a more general approach is considered to standardize a method within a laboratory. An assay was evaluated using over 20 model drugs to assess its ability to classify drugs as high or low permeability. This cell culture method is considered to be useful as it established a relationship between experimental permeability values and extent of absorption. This represents an application of regulatory specifications to demonstrate that a cell model is able to determine the permeability class of a drug substance.

Notes

[6] Center for Drug Evaluation and Research, Food and Drug Administration. Guidance for Industry. “Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System,” 2000.