DISSOLUTION TEST FOR ORAL DOSAGE FORMS

Reference standards: USP, BP or Ph. Eur

Overview

A dissolution test evaluates the drug's performance in vitro, simulating how it might dissolve in the gastrointestinal tract after administration.

While the International Pharmacopoeia provides specific guidelines on relevant pharmaceutical substances, test apparatus, dissolution media, temperature, stirring speed, and acceptance criteria for various drug products, it lacks a monograph for relevant finished product standards. Dissolution test should be included in the supplier's finished product specification in accordance with USP, BP or Ph. Eur. If the relevant monograph does not specify otherwise, the finished product can be considered compliant if the requirements if not less than 75% of the labelled content of iron and folic acid from the tablets are dissolved in 1 hour.

Link to Document

INTERNATIONAL PHARMACOPOEIA DISSOLUTION TEST FOR ORAL DOSAGE FORMS

RESOURCES - DISSOLUTION METHODS DATABASE: | USP