

# Comparative dissolution testing

## Dissolution conditions (**study design**)

Apparatus (choice)	<ul style="list-style-type: none"> <li>• Paddle, 50 (75) rpm or</li> <li>• Basket, 100 rpm</li> </ul>
Dissolution media  All three media for full comparison	<ol style="list-style-type: none"> <li>1. Buffer pH 6.8 <u>or</u> simulated intestinal fluid without enzymes</li> <li>2. Buffer pH 4.5</li> <li>3. 0.1 M HCl <u>or</u> buffer pH 1.2 <u>or</u> simulated gastric fluid without enzymes</li> </ol>
Volume of media	900 ml or less
Temperature	37°C ± 0.5°C
Sampling points	10, 15, 20, 30, 45, (60, 120) min. (typical)
Units (individual)	12 for "official" studies

# Dissolution Testing Guidelines

**L Reisser**



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