

# Dissolution Tester Calibration and Validation: Ensuring Precision in Pharmaceutical Testing

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## listing Summary

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Dissolution testing plays a vital role in evaluating the performance of oral solid dosage forms, particularly tablets and capsules. It provides critical data about the rate and extent to which the active pharmaceutical ingredient (API) is released into a solution. This article outlines the key steps involved in the calibration and validation process, ensuring your pharmaceutical testing practices are compliant, consistent, and credible. **Importance of Calibration and Validation** Calibration and validation of a dissolution tester ensure that the equipment performs within specified limits and provides accurate, reproducible results. Regulatory agencies such as the FDA and USP (United States Pharmacopeia) mandate strict compliance with calibration and validation procedures. Inaccurate dissolution results can lead to regulatory issues, product recalls, and compromised patient safety. **Calibration Process** Calibration involves verifying that the dissolution tester meets defined mechanical and operational specifications. The primary parameters assessed during calibration include:

- **Rotation Speed Verification:** Ensure the paddles or baskets rotate at the correct speed using a calibrated tachometer.
  - **Temperature Accuracy:** Confirm that the dissolution medium maintains a constant temperature (usually  $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ ) using a certified thermometer.
  - **Vessel Centering and Shaft Alignment:** Mechanical checks are done to ensure the paddles or baskets are properly aligned and centered in the vessels.
  - **Timer Functionality:** The built-in timer should match an external calibrated timer.
- Validation Procedure** Validation proves that the system performs as expected under actual operating conditions. It includes:
- **Installation Qualification (IQ):** Verifying the system is installed correctly and according to manufacturer specifications.
  - **Operational Qualification (OQ):** Ensuring the system functions correctly under defined parameters.
  - **Performance Qualification (PQ):** Using USP-calibrated Prednisone tablets or other standard reference materials to test system performance and repeatability.

**Maintaining Compliance** Regular calibration and validation should be scheduled based on the frequency of use, manufacturer recommendations, and GMP (Good Manufacturing Practice) requirements. Detailed documentation must be maintained to track calibration dates, equipment performance, and any corrective actions taken. **Conclusion** Proper calibration and validation of dissolution testers are critical steps in pharmaceutical quality control. They guarantee accurate, repeatable results and help manufacturers maintain regulatory compliance. A well-maintained dissolution system not only ensures product integrity but also builds trust in pharmaceutical testing processes.

