

Whitepaper FDM

HUMIDITY CONTROL FOR PHARMA TESTING: BEST PRACTICES

Executive Summary

Precise humidity control is a cornerstone of pharmaceutical testing. From stability studies to raw material validation, maintaining constant relative humidity (RH) is vital for accuracy, compliance, and product safety. This whitepaper offers a practical guide to humidity control in pharma labs, including troubleshooting, sensor calibration, and maintenance.

Key Environmental Parameters

Humidity testing ensures pharmaceutical products remain stable, effective, and safe throughout their lifecycle. Critical parameters include:

- **RH Range:** 20% to 80% RH ($\pm 2\%$ stability)
- **Test Conditions:** often combined with temperature (e.g., 25°C/60% RH or 40°C/75% RH)
- **Response Time:** rapid control to prevent overshoot
- **Sensor Placement:** strategic positioning for chamber uniformity

Advanced FDM chambers ensure uniform and accurate control across the test volume, crucial for ICH stability testing.

Troubleshooting Common Issues

Pharma labs often encounter fluctuations or drift in humidity levels. Typical causes and solutions include:

- **Sensor Drift:** recalibrate every 6–12 months
- **Leaks:** check chamber seals and water supply systems
- **Condensation:** improve airflow or adjust dew point setpoint
- **Software Lags:** ensure firmware is updated for precision control

Proactive system checks reduce downtime and increase test reliability.

Sensor Calibration and Monitoring

Reliable RH control depends on properly calibrated sensors. Best practices:

- Use reference hygrometers (traceable to national standards)
- Calibrate at multiple RH levels (e.g., 30%, 60%, 75%)
- Log calibration history and verification frequency
- Ensure compatibility with GLP/GMP documentation standards

FDM supports calibration workflows with integrated ports and user-accessible sensor zones.

Maintenance of Humidity Control Systems

Long-term performance requires routine maintenance:

- **Water System:** use demineralized water to prevent mineral buildup
- **Humidifiers/Dehumidifiers:** inspect for microbial growth and clean regularly
- **Drain Lines:** check for blockages
- **Filter Replacement:** follow manufacturer schedule

Preventive maintenance helps ensure GMP compliance and protects test integrity.

Conclusion

Effective humidity control is non-negotiable in pharmaceutical testing. FDM's climate chambers combine precision engineering and intuitive control interfaces to help laboratories maintain stable, compliant test environments. With proper setup, calibration, and care, labs can minimize risk and maximize data reliability.

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