

# Humidity validation and compliance in food and pharmaceutical manufacturing

## Application background

Pharmaceutical manufacturers need to ensure their practices comply with the FDA's CFR 21, part 11 (in the US) or annex 11 (in the EU). This specifically relates to the 'creation, modification, archival, retrieval and transmission of any electronic records' required by the FDA.

Because the control of humidity is vital for many processes in pharmaceutical manufacturing, there are a large number of probes in use at any time – all of which will need to be regularly calibrated to ensure accuracy. Sending RH probes away for calibration is a time-consuming exercise for both food and pharmaceutical companies, but is often seen as necessary if the CFR 21, part 11 regulations are to be met.

## Simple on-site validations

While many companies opt to set up their own, in-house humidity calibration laboratories, this is not an option for all manufacturers because the capital expense and resources needed to manage it. However, there are affordable alternatives.

Michell Instruments offers a cost-effective humidity validator which enables food and pharmaceutical companies the option to save time and money on recalibrations, paying back the cost of the instrument in a few months. The HygroCal100 is unique in its class. As well as being completely portable, it has data logging and documenting capabilities making it compliant with CFR 21 part 11.

It is extremely easy to use and inexpensive to maintain. For full, traceable calibrations it can be used in combination with a chilled mirror reference hygrometer. Although any hygrometer can be used, Michell offer the HygroCal100 and Optidew Vision as a complete package for fully documented, traceable calibrations.

The HygroCal100 is also compatible with most relative humidity and temperature probes available on the market: users are not limited to only certain brands or sizes. Up to seven probes can be validated at a time, and users can choose to operate manually or use an automated programme.



## Highlights:

- Portable and self-contained: weighs just 3.2kg
- Intuitive user interface for automated probe verification
- Integral battery pack for validation without access to external services
- Validate 7 probes simultaneously
- Automated validation procedures for complete hands-off probe verification
- Internal calibration correction cycle ensures continued confidence
- Optional chilled mirror reference hygrometer, allowing use as a calibrator
- Download logged verification data direct to USB memory

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