AccuFlux® in the Lyophilization Process

Millrock Technology, Inc has pioneered the use of heat flux sensors to measure and control the heat transfer dynamics of the freeze drying process using real measurement in real time. This unique technology provides measurement of the critical process parameters in all stages of the freeze drying process, including freezing, primary drying, and secondary drying. AccuFlux enables the user to analyze, improve and optimize their freeze drying processes in the lab and more easily transfer the protocols to production.

AccuFlux provides direct measurement of vial thermal conductivity (Kv) and heat transfer parameters (heat flux, mass flow, product temperature, cake resistance etc).

Heat flow, like Kv, is dependent on all of the conditions in the freeze dryer and the product.

“...on the value of Kv, which can vary with operating conditions, type of container, equipment and configuration used for loading the product” Pisano, Fissore and Barresi, Dipartimento di Scienza Dei Materiali e Ingegneria Chimica, Politecnico di Torino Italy.

Changing any one variable (such as but not limited to fill volume, containers, pressure etc) will change heat flow and Kv. There is also some variation of these factors within a batch (ie all tubular vials for example are not exactly the same, even if they are from the same manufacturer purchased at the same time--there are tolerances of glass thickness etc).

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Kv = \frac{\text{Heat Flux}}{(T_s - T_b)}
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Measurements vs Assumptive Calculations

Heat flow measured, not calculated.
Shelf temperature measured right at the surface
Temperature of the product at the bottom on the vial measured.

Measure your critical process parameters and develop optimized and transfersable protocols.
AccuFlux directly measures heat flow in all phases of the freeze drying process and provides information that has never been available before, such as:

**FREEZING**
- Heat removed during the freezing process
- % of the free water frozen by controlled nucleation
- Heat flow during ice crystalization
- Heat flow control post-nucleation for crystal growth controls
- End of freezing as indicated by heat flow.
- Measures actual heat flow

**PRIMARY DRYING**
- Product temperature during primary drying
- Kv determined from actual measurements—no assumptive calculations
- Cake resistance to vapor flow
- Mass flow
- % dry
- End of Primary Drying
- End of Secondary Drying

AccuFlux provides the greatest insight to your product when used in conjunction with a controlled nucleation such as Millrock Technology, Inc.'s FreezeBooster.