AccuFlux®

Heat Flow Measurement and Control for Lyophilization

AccuFlux in the Lyophilization Process

Millrock Technology, Inc has pioneered the use of heat flux sensors to meausre and control the heat tranfer dynamics of the freeze drying process using real measurment 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).

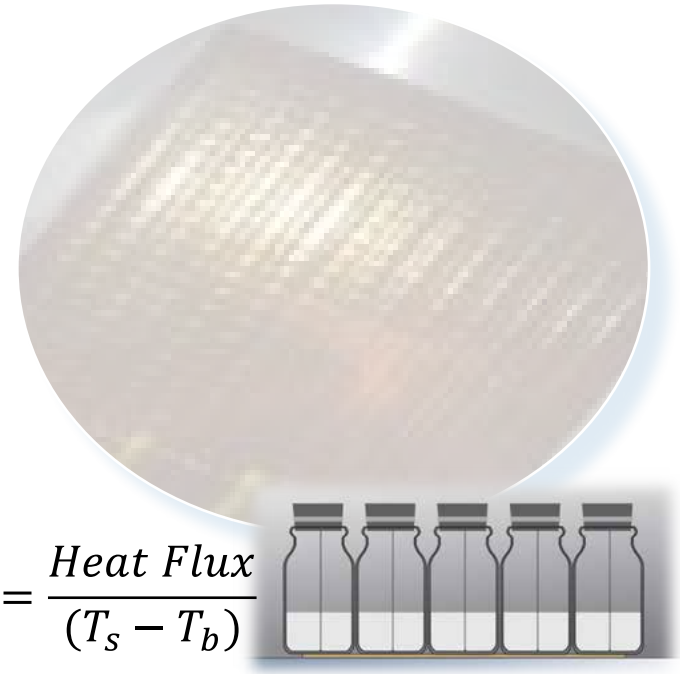
Heat flow, like Kv, is dependent on all of the conditions in the freeze dryer and the product.

> *"...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, Dipartment di Scienza Dei Materiali e Ingegneria Chemica, Polticenico 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).

Stop Calculating Heat Flow - Measure It!

- Real time in process measurement.
- Control primary drying with or without product thermocouples.
- Optimize heat flow during the freeze drying process.
- Process Analytical Technology in real time.
- Control post nucleation ice crystal growth (use with controlled nucleation).



$$Kv = \frac{Heat\ Flux}{(T_s - T_b)}$$

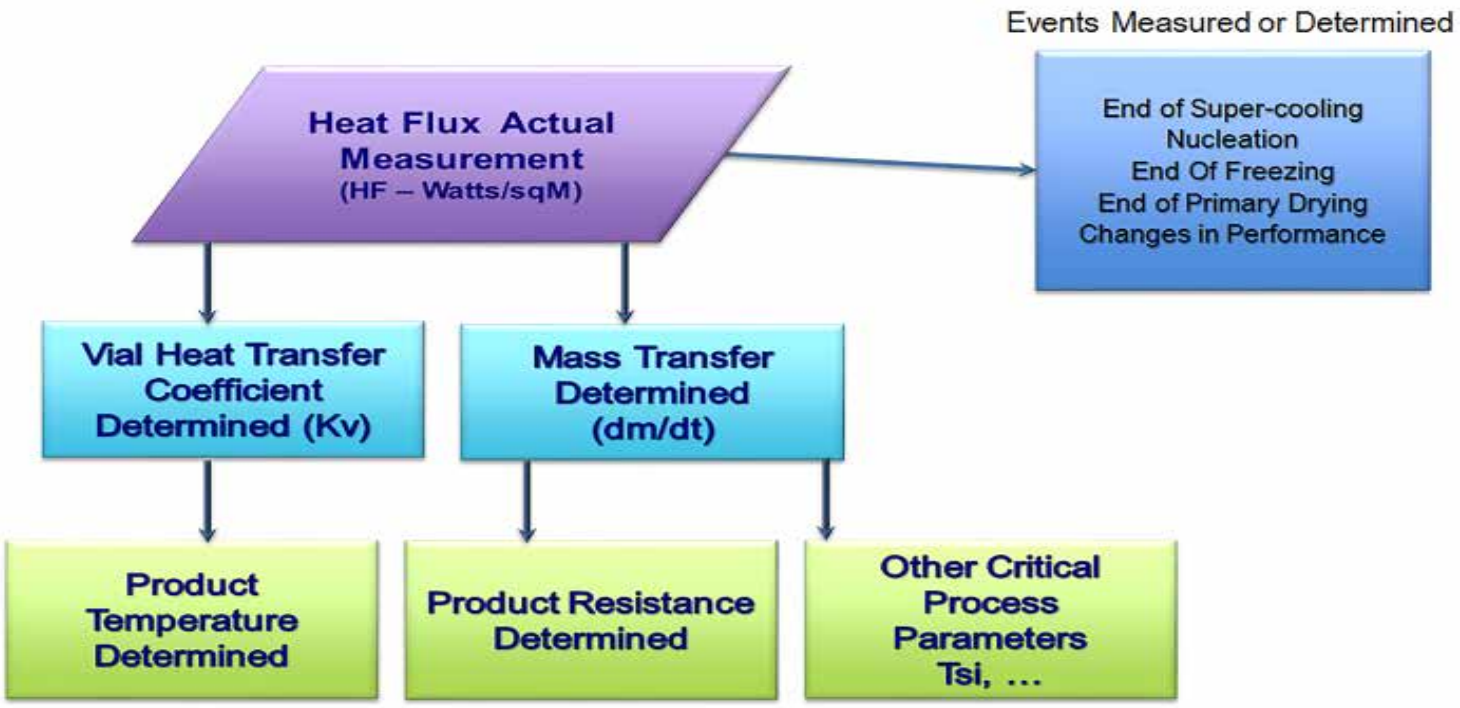
Measurements vs Assumptive Calculations

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

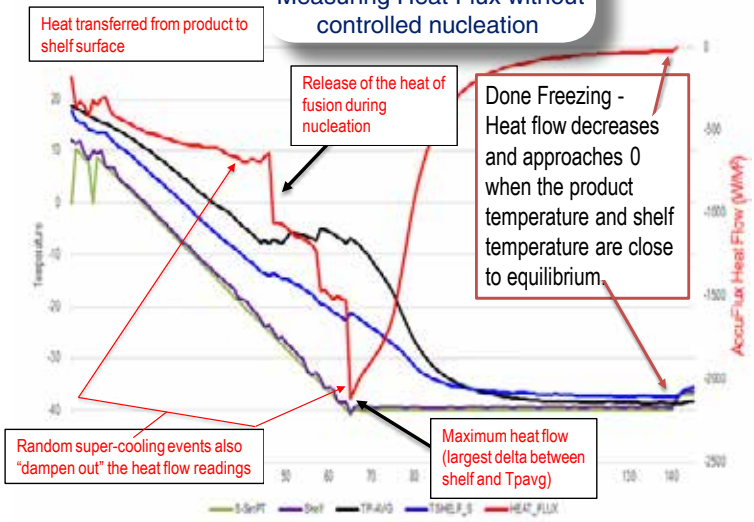
Measure your critical process parameters and develop optimized and transfersable protocols.

AccuFlux®
Heat Flow Measurement and Control

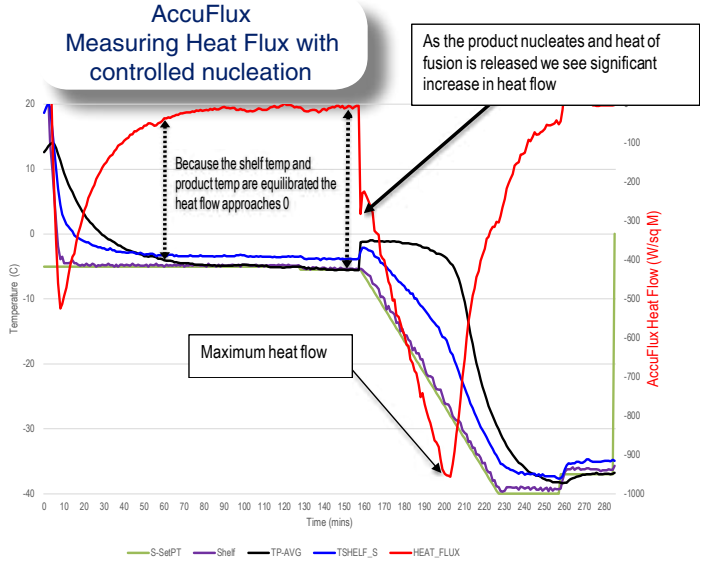
MILLROCK TECHNOLOGY
millrocktech.com



AccuFlux
Measuring Heat Flux without controlled nucleation



AccuFlux
Measuring Heat Flux with controlled nucleation



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 crystallization
- 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 conjuction with a controlled nucleation such as Millrock Technology, Inc.'s FreezeBooster

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Specifications subject to change without noticifation. All specifications based on 20C ambient and 60 Hz
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