Designation: E3250 – 21

Standard Practice for Product Temperature and Equipment Pressure Instrumentation in Pharmaceutical Freeze Drying[1]

This standard is issued under the fixed designation E3250; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 Recommended best practices in monitoring of product status during pharmaceutical freeze drying are presented focusing on methods that apply to both laboratory and production scale.

1.2 With respect to product temperature measurement, sources of uncertainty associated with any type of measurement probe are discussed, as well as important differences between the two most common types of temperature-measuring instruments — thermocouples and resistance temperature detectors (RTD). Two types of pressure transducers are discussed — thermal conductivity type gauges and capacitance manometers, with the Pirani gauge being the thermal conductivity type gauge of choice. It is recommended that both types of pressure gauge be used on both the product chamber and the condenser for freeze dryers with an external condenser, and the reasoning for this recommendation is discussed.

1.3 Aseptic filling and sterilization practices are outside the scope of this practice. These are recommendations to assist users in selecting best practices and they are not intended to supersede or replace regulatory requirements.

1.4 *Units*—The values stated in SI units are to be regarded as the standard. No other units of measurement are included in this standard with the exception of mTorr for pressure measurement

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E230 Specification for Temperature-Electromotive Force (emf) Tables for Standardized Thermocouples

2.2 *ICH Standard:*[3]

ICH Q8(R2) Pharmaceutical Development

3. Significance and Use

3.1 This practice deals with recommended best practices for freeze dryer instrumentation, particularly which is used for monitoring the status of the product during freeze drying and perhaps for equipment capability testing. Temperature and pressure are both critical variables affecting heat transfer, mass transfer, process efficiency, and product quality. For this reason, particular emphasis is placed on product temperature and pressure measurement within the freeze dryer. The methods discussed in this guide are limited to techniques that are equally applicable at both laboratory and production scale.

3.2 Finally, it is recognized that "best practice" changes over time as new technology matures and process understanding deepens.

4. Product Temperature Measurement

4.1 When developing a freeze-dry cycle for any product, it is essential to collect reliable data on product temperature throughout the freeze-dry process. It shall be ascertained that the product is frozen to a suitably low temperature and held at that temperature for a sufficient time to ensure complete product freezing and equilibration with the frozen temperature. Identifying appropriate conditions for primary drying, which is usually the longest part of a freeze-dry cycle, requires knowledge of the equipment limit and the upper product temperature limit for primary drying be established based on materials characterization backed by stability studies, and that the product temperature during primary drying remain a safe

[1] This practice is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee E55.05 on Lyophilization.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Secretariat, Route de Pré-Bois, 20, P.O Box 1894, 1215 Geneva, Switzerland, https://www.ich.org.

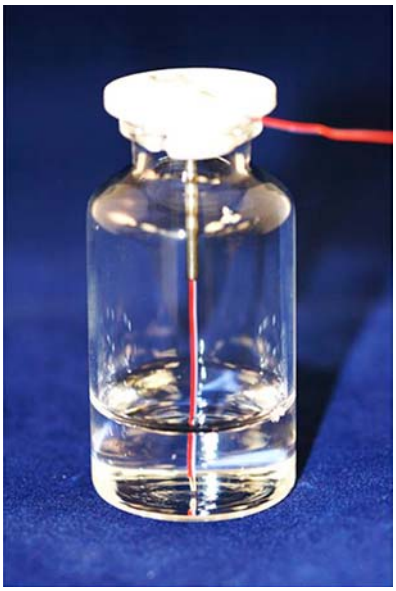

FIG. 1 Best Practice for Measuring Product Temperature in Individual Vials includes Using Fine-Gauge Thermocouple Wire along with a Device for Maintaining the Location of the Tip of the Thermocouple in the Center of the Vial Touching the Bottom

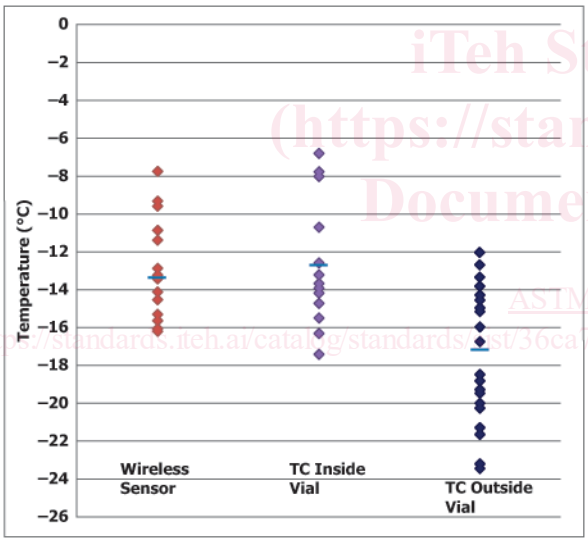

FIG. 2 Comparison of Ice Nucleation Temperatures for Vials Containing a Temperature Probe Versus Vials in which the Temperature Probe is Attached to the Outside surface of the Vial

margin below this upper limit without being unnecessarily low resulting in an unnecessarily prolonged freeze-dry cycle.

4.2 The recommended best practice for measuring product temperature in individual vials is illustrated in Fig. 1. Several features should be evident. First, the thermocouple wire is thin (30 gauge, in this case). The fine wire facilitates handling the lead wire in such a way that it does not disrupt vials in its path and helps in locating the junction at a precise location. Note also that there is a device in the neck of the vial incorporating a guide tube through which the thermocouple wire is threaded. This enables locating the thermocouple tip in the center of the vial and touching the bottom. (Additional details of the device are in X1.1 and illustrated in Fig. 1).

4.3 While there is no question of the importance of product temperature monitoring during laboratory scale cycle development, practices across the industry differ widely over the use of product temperature beyond the laboratory scale. There is widespread recognition of the usefulness of monitoring product temperature during scale-up to assure that the time course of product temperature at larger scale is reasonably consistent with laboratory scale data. The same consideration applies to cycle validation, stability batches at larger scale, transfer of cycles between manufacturing sites, manufacture of clinical supplies, and so forth.

4.4 Before going further, it is important to discuss some of the problems and sources of uncertainty associated with product temperature measurement. First, the presence of any temperature probe introduces a bias in monitored vials relative to non-monitored vials. The temperature-measuring device, regardless of whether it is a thermocouple, a resistance temperature detector (RTD), or any other type of device, can act as a nucleation site for ice. This is illustrated in Fig. 2 in which nucleation temperatures for vials with a temperature probe in the vial are compared with nucleation temperatures with the temperature probe fastened to the outside surface of the vial where it cannot influence nucleation. (The details are in X1.2). As a result, monitored vials tend to sublime more rapidly than the rest of the batch. Ten percent faster is a reasonable estimate **(1)**.[4] Note, this estimate to quantify the bias should not be assumed for all product/vial/thermocouple combinations, and is provided merely as an estimate. This bias shall be taken into account in establishing the end of primary drying in cases in which product temperature is the only cycle end-point indicator. This issue is most important for stochastic ice nucleation; that is, nucleation of ice proceeds randomly when an array of vials is placed on a cooled shelf. As the technology matures for controlled nucleation in freeze drying, using either rapid depressurization **(2)** or introduction of an ice fog **(3)**, we can expect that there would be less bias between monitored vials and the rest of the batch.

4.5 In addition to the bias introduced by temperature-measuring devices, there are other sources of uncertainty in the integrity of product temperature data that are particularly prevalent in a production environment. Fig. 3 is a photograph of product thermocouples that are commonly used in a production setting. There are at least two things "wrong with this picture." First, there is no provision for securing the tip of the thermocouple in a fixed position in contact with the product. Second, the heavy gauge of the thermocouple wire and the consequent stiffness and weight of the wire adds to the uncertainty as to exactly what temperature is being measured. (The details are in X1.3).

4.6 A significant logistical problem with temperature monitoring in a production environment is the use of automated loading/unloading systems. Such systems give limited, if any,

[4] The boldface numbers in parentheses refer to a list of references at the end of this standard.

FIG. 3 Thermocouples are Representative of Thermocouples Commonly Used in a Production Environment for Product Temperature Measurement

access to vials for insertion of temperature probes. Some manufacturing systems use sub-doors on the front of the freeze dryer ("pizza" doors), in which, after a shelf is loaded, the shelf stack indexes upward, and that shelf is no longer accessible for manually placing probes in vials. This is the primary reason why product temperature is not monitored during routine production but merely used during engineering runs as a part of process validation and Technology transfer. Note that the above section does not imply that monitoring product temperature is not important. However, given the bias introduced by monitoring with thermocouples in the vial, logistical challenges associated with such measurement in the aseptic environment, and that the temperature can be monitored as a part of the engineering run, the data can be used to augment the need for monitoring during routine production.

4.7 Another disadvantage of product temperature probes in a production setting is that insertion of any type of probe into an open container of product is usually a manual operation. Regardless of the care taken to maintain asepsis, this type of operation cannot help but compromise sterility assurance to some extent. For this reason, in many production operations, temperature probes are placed only in vials on the front row of the freeze dryer, since this can be done without reaching over the tops of partially open vials of product. While this is good practice from the standpoint of sterility assurance, the front row is a non-representative location because of the "edge-effect," in which vials on the edge of an array of vials, particularly the edge near the door, receive additional heat via thermal radiation (**4**).

4.8 *Thermocouples Versus RTDs:*

4.8.1 A thermocouple consists of two wires made from different metals joined together at one end to form a measuring junction. The opposite ends, connected to a thermocouple meter, are referred to as the reference junctions. When the two ends are placed at different temperatures, a voltage difference develops along each of the thermocouple wires. The difference between the voltage generated by the two wires is the voltage measured between the two reference junctions. This is known as the Seebeck effect. While any two metal combinations behave in this way, only a few combinations are important industrially (refer to Specification E230). Some examples are shown in Table 1.

4.8.2 The Type T thermocouple seems to be the most commonly used thermocouple in freeze drying. (The details are in X1.4.) Regular replacement of thermocouples should be considered, and of course, any thermocouple registering an open circuit should be discarded.

4.8.3 Given that thermocouples generate only tens of microvolts per degree temperature difference between the measurement junction and the reference junction, it is important to avoid introduction of any metal other than the appropriate thermocouple materials anywhere in the circuit, particularly in

TABLE 1 Examples of Thermocouple Composition

Type	Materials	Sensitivity (Average μV/°K)	Comments
S	Platinum/platinum + 10 % rhodium	10	Loses sensitivity at low temperature.
T	Copper/constantan	43	The most commonly used thermocouple in freeze drying.
K	Chromel/alumel	41	Most common general-purpose thermocouple.
E	Chromel/constantan	68	Highest e.m.f. output of any thermocouple. Good for low temperatures.
J	Iron/constantan	50	Wires become brittle at low temperatures.

areas in which there are large temperature gradients. Connectors and feedthroughs should be constructed only of thermocouple materials. It is also important to route thermocouple wires such that they are not near wires carrying a large current because the large current can induce a current in the thermocouple circuit causing systematic errors.

4.8.4 An RTD is based on the idea that the resistance of a metal varies in a precise and reproducible way with temperature. A common type of RTD is a 100 ohm platinum wire wound around a core material and covered with some type of sheath (Fig. 4). Other types of RTDs in common use consist of a film of platinum on a solid substrate. This wire is placed on one side of a Wheatstone bridge circuit with the other side incorporating a reference resistor carrying the same current. RTDs are better than thermocouples in terms of accuracy, precision, linearity, and stability. For this reason, temperature measurement at fixed points in a freeze dryer, such as in the heat transfer fluid at the inlet manifold to the shelves, on the condenser, and in the drain lines, are usually RTDs. An attribute of thermocouples that makes them particularly useful for product temperature measurement, however, is that the thermocouple measures temperature at the point at which the two wires are joined, that is, it is a "point" measurement. An RTD measures the average temperature over the area of the sensing element. As discussed previously, it is important to monitor the product at the warmest point, which is at the bottom of the frozen material. As seen in Fig. 4, the temperature measured is the average temperature of the exposed area of the element. For this type of sensor, the measuring element is partially immersed in the frozen matrix and partially embedded in the partially dried solid for most of primary drying, so the average temperature would be misleading.

4.8.5 Some newer RTD systems incorporate much smaller sensing elements than older RTD systems, which tend to be relatively bulky. The larger the sensing element, the larger the discrepancy between the RTD and a thermocouple. An example of more recent RTD-based technology is the data logger (Ellab, Hilleroed, Denmark) shown in Fig. 5. Note the small sensing element. Of course, as the size of the sensor decreases, the more closely the measurement approaches a "point" measurement. Provided that the sensor is located in the bottom of the vial, the smaller sensor minimizes the problem of the sensor being partially embedded in frozen material and partially embedded in the dried layer. In fact, there is probably an optimum sensor size that combines the advantages of "point" sensing of a thermocouple with the relative insensitivity of the measuring element to small changes in the position of the sensor (see Note 1). With the data logger shown in Fig. 5, there is still a lead wire from the sensing element to the logger, so the same consideration would apply to incorporating a device to secure the sensing element in the middle of the vial touching the bottom. The logger shall also be positioned in such a way that it does not interfere with freeze-drying operations, such as stoppering.

FIG. 4 100 Ω Platinum RTD Sensor

NOTE 1—It is typical for freeze dryers to use thermocouples for product temperature monitoring and RTDs for process control. There is no industry standard with respect to calibration frequency or the number of reference temperatures to be used for calibration. RTDs, having a much more linear response than thermocouples, require fewer temperature points for calibration. A typical procedure is to place temperature probes in a stirred liquid reference bath (liquid is preferred over "dry" baths because of better temperature uniformity in liquid baths as well as better thermal contact with the sensor). Calibration points in the range of –50°C to –20°C, –20°C to 0°C, and 110°C to 130°C are representative. The temperature indicated on all system devices, such as recorder, controller, and control system displays, should be within 0.5°C of each reference temperature. If not, the system needs to be adjusted accordingly. If an adjustment is needed at any reference temperature, then accuracy at each of the other temperatures needs to be rechecked. We recommend a risk-based approach to the calibration frequency. For example, a typical calibration frequency is every 30 freeze dry cycles or every 3 months, whichever comes first.

4.9 *Recommended Best Practice for Product Temperature Measurement:*

4.9.1 Best practice with respect to product temperature measurement can be summarized as follows:

4.9.1.1 Despite the fact that RTDs are, in many ways, superior to thermocouples, thermocouples are preferred for product temperature measurement because of the ability to measure temperature at a precise point. The most appropriate point to measure product temperature is in the center of the vial with the tip of the thermocouple touching the bottom of the vial.

4.9.1.2 Fine-gauge thermocouple wire is preferred because of the flexibility of the wire and the ability to locate the tip of the thermocouple in a precise location, for example, for small fill volumes in small vials, a 36-gauge (0.13 mm) thermocouple is a good choice. For larger fill volumes in larger vials, a somewhat larger gauge, such as 30 (0.25 mm), would be appropriate.

4.9.1.3 Use some type of device to hold the thermocouple in place within a monitored vial. The open area of this device should be very close to that of a partially stoppered vial.

4.9.1.4 Be aware of the sources of uncertainty associated with product temperature measurement in a manufacturing setting and do not overinterpret such data.

4.9.1.5 Be aware of the bias in freezing and freeze-drying behavior caused by any temperature-measuring device. Recognize that monitored vials may freeze dry significantly faster

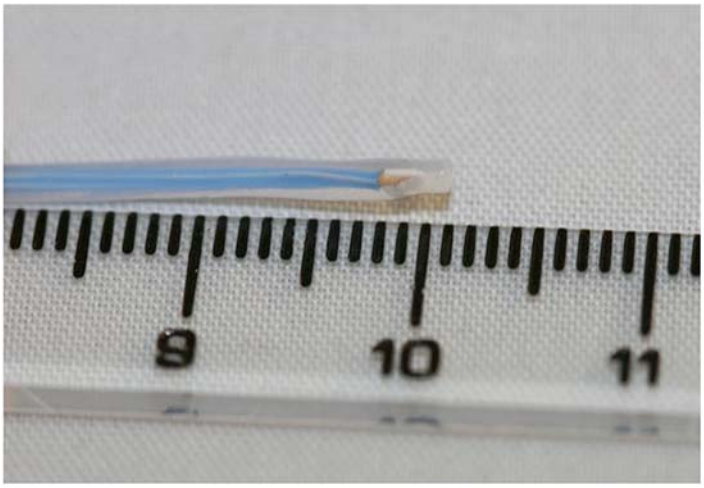

FIG. 5 As RTD Sensing Elements Become Smaller, as Shown Here for a Temperature Data Logger (Ellab), They More Closely Approximate a "Point" Temperature Measurement

than the rest of the batch. The same best practices that apply at the laboratory scale should also apply in a manufacturing environment.

5. Chamber Pressure Measurement in Freeze Drying

5.1 There are many types of pressure transducers and a review of all of them is beyond the scope of this practice. The focus is on two types: thermal conductivity type sensors and the capacitance manometer. Both types are commonly used in pharmaceutical freeze drying but are often not applied in the most useful way.

5.2 *Thermal Conductivity Type Gauge:*

5.2.1 There are two basic types of thermal conductivity type pressure gauge: a thermocouple gauge and a Pirani gauge. The thermocouple gauge consists of a thermocouple spot-welded to a heated filament. The filament, fed by a constant current, reaches a temperature determined by the rate of energy loss from the filament by a combination of thermal radiation and conduction through the process gas. Energy loss by thermal radiation is kept small by using a filament with a low thermal emissivity, such as platinum. The higher the pressure in the system, the more rapid the rate of energy loss from the filament. The output of this gauge is nonlinear, and the useful pressure range is rather small, only about two orders of magnitude. Thermocouple pressure gauges are usually found on the less expensive laboratory scale freeze dryers.

5.2.1.1 In the Pirani gauge, two filaments are used as the two "arms" of a Wheatstone bridge. One filament is the reference filament maintained at constant pressure and gas phase composition. The other filament is the measurement filament. In the Pirani gauge, the filament temperature is controlled at a constant value, and the current needed to do so is monitored. A Pirani gauge has about 100 times the useful range of a thermocouple gauge and is, thus, the preferred thermal conductivity type instrument for freeze drying.

5.2.2 An important characteristic of any thermal conductivity type gauge is that the response is a function of the composition of the vapor phase being monitored. This is important in freeze drying because the composition of the gas phase in the chamber changes dramatically from being essentially 100 % water vapor during the primary drying phase to essentially 100 % nitrogen (or whatever gas is being bled into the chamber to control pressure) late in secondary drying. The free molecular conductivity of water vapor is about 60 % higher than the free molecular conductivity of nitrogen (**5**). This characteristic can be used as an advantage as a process monitoring tool, explained in 5.2.3 and 5.2.4.

5.2.3 It is important to understand that thermal conductivity type gauges use a hot filament. This brings up a safety concern when freeze drying formulations containing an organic solvent, such as t-butanol. (The details are in X1.5). It is considered best practice to turn off thermal conductivity type gauges when freeze drying products containing an organic solvent. Alternatively, the product chamber could be evacuated and purged with nitrogen before starting freezing.

5.2.4 It is important to be aware that different Pirani gauges vary in their robustness to repeated steam sterilization. There are no controlled studies to determine the mechanism of failure. Possible modes of failure could be over-pressurization (the upper pressure limit for most Pirani gauges is about 1000 Torr) or exposure to excessively high temperature. However, it is likely that the ability to withstand repeated steam sterilization has more to do with the composition of the filament. Several filament compositions are used, including tungsten/rhenium, platinum/iridium, platinum/rhodium, platinum, and gold-plated tungsten. A gauge designed for corrosive environments has been tested. This gauge uses a platinum/iridium filament and was demonstrated to withstand 80–100 steam sterilization cycles. This gauge has still not failed, although it is steam sterilized less frequently. In contrast, another gauge was tested, which uses a gold-plated tungsten filament. This gauge failed after two or three sterilization cycles. It is prudent to assume that a Pirani gauge will fail at some point and require replacement, but it is important to be careful in selection of the gauge.

5.3 *Capacitance Manometer:*

5.3.1 All capacitance-based gauges work in one of two ways, either by keeping the geometry of the system constant and allowing the dielectric constant to vary or a variable geometry with a constant dielectric constant. The latter mechanism is the basis for the capacitance manometer pressure gauge. There are two sides of the transducer: a reference side that is evacuated and sealed at a very low pressure of around 10^{-7} Torr and a measurement side that is exposed to the process. The sides are isolated by a metal diaphragm, typically Inconel, a high-quality stainless steel. As the process pressure changes, the diaphragm flexes changing the geometry and, therefore, the capacitance, of the instrument. Capacitance manometers are the instrument of choice for pharmaceutical freeze drying because of their wide useful range (about four orders of magnitude), accuracy, stability, and linearity. Another compelling feature is that a capacitance manometer measures true pressure, force per unit area, independent of gas phase composition. It is best practice to use a heated transducer to avoid the possibility of water vapor condensation inside the gauge, perhaps from steam sterilization, and avoid the potential for zero drift caused by variation in ambient temperature.

5.4 Best practice for monitoring the pressure in the chamber and condenser of a freeze dryer is to have both a capacitance manometer and a Pirani gauge on both the chamber and the condenser. This configuration enables what has come to be called comparative pressure measurement. In this process analytical method, the chamber pressure is monitored and controlled using the capacitance manometer. Simultaneously, pressure is monitored using the Pirani gauge. This technique takes advantage of the gas phase composition dependence of the Pirani gauge in which the change in output of the gauge reflects the change in gas phase composition as the process transitions from primary drying to secondary drying. An example of this type of process data is shown in Fig. 6.

5.5 The higher apparent pressure during primary drying as measured by the Pirani gauge reflects the higher thermal conductivity of water vapor, which makes up nearly all of the vapor phase in the chamber during primary drying. As sublimation of ice is completed, the apparent chamber pressure drops. The width of the transition region from pseudo steady state during primary drying to equilibration with the capacitance manometer is a measure of the vial-to-vial consistency in primary drying rate, the more uniform the vial-to-vial sublimation rate, the sharper the apparent pressure drop during the transition. For example, the “edge effect” in which vials at the edge of an array of vials dry faster than the vials in the center of an array would be reflected in a more gradual decrease in apparent pressure at the end of primary drying. It is considered good practice to wait until the Pirani reading has nearly reached the capacitance manometer reading before increasing the shelf temperature for secondary drying. In general, a difference in pressure readings of 5–10 mT seems to work well as long as the steady state pressure during primary drying is more than about 40 mT. Note that a difference between the Pirani reading and capacitance manometer in a clean, dry empty chamber results typically from a calibration offset between these pressure gauges. It is, therefore, a good idea to measure this difference/correct in advance. Some freeze dryer manufacturers offer the very useful option of sequencing the cycle from primary to secondary drying based on the difference in apparent pressure between the capacitance manometer and the Pirani gauge.

5.6 The main advantage of comparative pressure measurement is that it does not depend on monitoring of individual product vials but rather the composition of the vapor phase in the chamber. The technique has proven to be sensitive, reliable, and robust. One note of caution is that, if any vials should fall from the shelf to the bottom of the dryer, thus drying at a

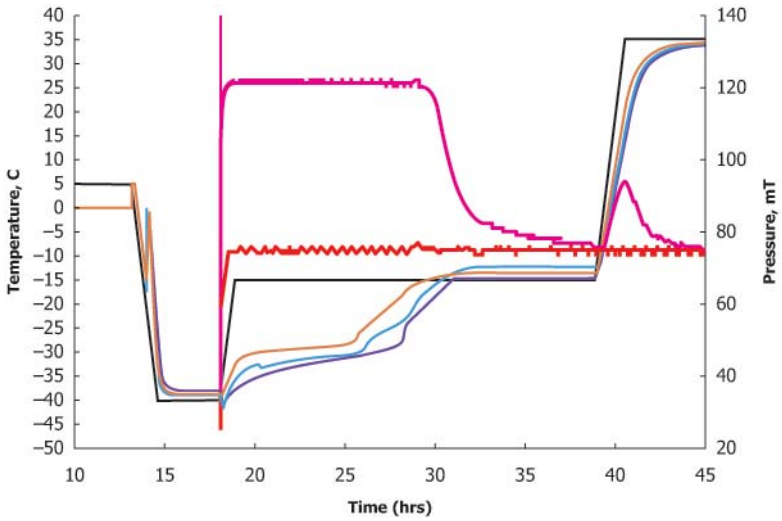

FIG. 6 Comparative Pressure Measurement as a Process-Monitoring Method: Pirani Gauge (Magenta), Capacitance Manometer (Red), Shelf Temperature (Black), and Other Lines are Individual Product Temperatures Measured by Thermocouples

non-representative rate, these vials can "fool" the Pirani gauge and give an abnormal response.

5.7 As shown in Fig. 6, comparative pressure measurement is also useful for monitoring the progress of secondary drying. Typically, there is a "burst" of water vapor from the product early in secondary drying as unfrozen water from the formulation is released at higher product temperatures. As the Pirani reading returns to the capacitance manometer reading, very little additional drying takes place at that shelf temperature as previously reported by Pikal, Shah, Roy, and Putman (**6**).

5.8 It is best practice to control chamber pressure based on the capacitance manometer simply because it measures true pressure independently of vapor phase composition. A capacitance manometer is more accurate, linear, and stable than a Pirani gauge. Some operations carry out pressure control based on the Pirani gauge and detect the end point of primary and secondary drying by a rise in the pressure as measured by the capacitance manometer. This is not a good idea from the standpoint of process consistency and could cause problems in transferring process conditions from one manufacturing site to another, particularly if no one is paying attention to the details of pressure measurement and control. There is also a risk of exceeding the critical product temperature when carrying out the process close to the critical product temperature near the end of primary drying. As the relative partial pressure of water vapor decreases, nitrogen flow increases to maintain the set point. This results in an increase in absolute pressure, increased heat transfer, increased product temperature, and increased risk to the product.

5.9 Why put capacitance manometers on both the chamber and the condenser? This is primarily because the ratio of the chamber pressure to the condenser pressure can serve as a measure of equipment performance. Any freeze dryer has a maximum sublimation rate that it will support at any given pressure, and there is a general lack of quantitative understanding of equipment capability across the industry. There are several factors that can limit equipment capability: refrigeration capacity, condenser surface area, and an upper limit on the attainable shelf temperature. Another limiting factor has to do with "choked flow," first reported as a source of uncertainty in scale up of freeze drying by Searles (**7**). Briefly put, choked flow arises from the fact that there is a thermodynamically imposed speed limit on how fast water vapor can travel from the chamber to the condenser, the speed of sound.

5.10 An alternative way, at least in principle, to identify the choke point is the pressure ratio between the chamber and the condenser, particularly when a cylindrical duct connects the chamber to the condenser. For a cylindrical duct, the pressure ratio corresponding to the onset of choked flow is 3:1 (**8**). Choked flow would not apply to freeze dryers with an internal condenser design. Some newer freeze dryers have a different chamber/condenser configuration in which the condenser is located beneath the chamber separated by a rectangular plate that is moved up and down hydraulically (Fig. 7). It would be very useful to be able to identify the choke point by measuring the chamber-to-condenser-pressure ratio for this configuration.

5.11 Differential capacitance manometers are available though there is no evidence of their use in freeze-dry process monitoring. These instruments are used to measure pressure differences between different locations. They are commonly used in monitoring of pressure differentials in adjacent areas in the context of contamination control technology. However, there is no reason why differential capacitance manometers could not be used to monitor the pressure difference between the chamber and the condenser.

5.12 Finally, why is it a good idea to have a Pirani gauge on the condenser? Occasionally, there is a leak somewhere in the system that prevents any vacuum from being established (**9**).

FIG. 7 In This Freeze Dryer, the Condenser is Located below the Chamber Separated by a Hydraulically Actuated Plate