LyoDictionary

Search For Common Lyophilization Terms Using Our LyoDictionary

A

Absorption
The taking in or trapping by physical forces of a substance (the sorbate) that penetrates another (the sorbent).

Adsorption
The taking up or trapping of a gas or liquid by attachment to surfaces, for example those of the freeze dryer, the container for the freeze-dried product.

Aerosol
A particulate suspension in air.

Air/Gas Bleed
The continuous or intermittent admission of air, or a selected gas, to a system undergoing continuous evacuation.

Amorphous
A solid of non-crystalline and therefore structureless nature.

Ampoule
A small glass container for chamber or manifold freeze-drying often shaped with a closed bulk and relatively long, sometimes constricted and prescored neck for closure by fusion (heat) sealing.

Ampoule Drying
Freeze-drying or other drying of material in ampoules.

Annealing
Tempering, conditioning. In freeze-drying it is the controlled and generally limited warming of a frozen system with the intent to further develop an ice phase and/or crystallization of one or more other components capable of eutectic behavior.

Aqueous
Containing water.

Aqueous Solution
A mixed liquid system in which one or more substances has been dissolved in wate.

ASME
American Society of Mechanical Engineers.

ASME Code
The standard set forth by ASME, that is utilized to ensure a freeze-drying system, or other pressure vessel, can withstand internal, and in the case of freeze-drying systems, external forces developed as a result of steam sterilization, over a specific temperature range, with a specific material of construction, such as 316L stainless steel.

ASME Stamp
The official label issued by a licensed authority that indicates that a vessel meets ASME standards. The label is visible and permanently affixed to the pressure vessel.

Aseptic
An object or material that is free of viable organisms.

Atmospheric Pressure
The pressure exerted at the earth's surface by the atmosphere. For reference purposes a standard atmosphere is defined as 1 Bar or 760 Torr or millimeters of mercury or 760,000 microns of mercury or millitorr.

Avogadro's Law
Equal volumes of all gases at the same temperature and pressure contain the same number of molecules. Used for calculating the specific volume of a gas. It is hypothesized that there are 6.06 x 1023 molecules in a gram-molecular weight of any substance.

B

Back-Filling Gas
The gas used to fill product containers after freeze drying is complete and prior to their closure. Typically, an inert gas.

Back Streaming
A process that occurs in a freeze dryer with very low system pressures where mechanical pump oil vapors can migrate from the oil sealed vacuum pump back into the freeze dryer and can ultimately enter the product.

Bar
The units of pressure equal to the weight of a column of mercury.

Barometric Control
The use of barometric measurement of a temperature to control the freeze-drying process.

Barometric Measurement
The inference of the average temperature of all freeze-drying fronts at any stage of primary drying by the isolation of the drying chamber from an external condenser and the measurement of a static vapor pressure in the chamber, from which the average product temperature can be determined, by reference to tables.

Batch Control
The use of validated in-process sampling and testing methods in such a way that results prove the process has done what it purports to do for the specific batch concerned, assuming control parameters have been appropriately respected.

Blank-Off Pressure or Temperature

The ultimate lower pressure or temperature a system can obtain.

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The ultimate lower pressure or temperature a system can obtain.

Boiling Point

The temperature varying with pressure, at which a liquid boils, usually measured at standard atmospheric pressure.

Boyle's Law

For a perfect gas at constant temperature the volume of a given mass is inversely proportional to the pressure acting on it or exerted by it.

Breaking Vacuum

Admitting air or a selected gas into an evacuated chamber, while isolated from a vacuum pump, to raise the pressure towards or up to atmospheric.

C

C

Temperature measured in degrees Celsius.

Cake

The structure of the freeze-dried product at the end of drying.

Calibration

Demonstrating that a measuring device produces results within specified limits of those produced by a reference standard device over an appropriate range of measurements. This process results in corrections that are applied for maximum accuracy.

Calorie

A unit of heat equal to that required to raise the temperature of one gram of water from 14.5 to 15.5°C. A calorie is equal to 4.1868 joules. 1 Kcal equals 1,000 calories which equals 3.96 BTU.

Capacitance Gauge/Manometer

A form of vacuum gauge in which movement of a sensitive membrane is interpreted in terms of a variation in electrical resistance. Currently considered the most accurate method of pressure measurement for use in freeze dryers.

Certification

Documented testimony by qualified authorities that a system qualification, calibration, validation or revalidation has been performed appropriately and that the results are acceptable.

Circulation Pump

A pump for conveying the heat transfer fluid through shelves in a freeze dryer.

Cold Junction

Point of connection between thermocouple metals and the electronic instrument.

Cold Junction Compensation

Electronic means to compensate for the effective temperature at the cold junction.

Collapse

During freeze-drying the irregular shrinkage of, or loss of, an internal structure in the cake, sometimes accompanied by bubbling as the structure support of the ice crystals is withdrawn during sublimation. Collapse is associated with non-eutectic or amorphous freezing. It takes place in the freeze-drying front and continues until stopped by desorption. It can be stopped if the freeze-drying front is cooled below the threshold collapse temperature.

Conax Connection

A device to pass thermocouples or other wires through the wall of a vacuum tight vessel.

Collapse Temperature

(Tc). Typically measured by freeze dry microscopy. It is when the addition of energy to the product leads to a melting at the freeze dry - ice interface, sometimes resulting in cake shrinkage.

Condenser (Cold Trap)

In terms of the lyophilization process, this is the vessel that collects the moisture on a cold surface and holds it there as ice. The condenser protects the vacuum pump oil from contamination and in trapping out moisture helps with vacuum maintenance.

Condenser Chamber

A vessel connected to a freeze-drying chamber and containing the condenser.

Condenser/Receiver

In terms of refrigeration this unit condenses the hot refrigerant gas into a liquid and stores it under pressure to be reused by the system.

Contamination

In the vacuum system, the introduction of water vapor into the oil in the vacuum pump, which then causes the pump to lose its ability to attain its ultimate pressure.

Control Parameters

Those operating variables that can be assigned values that are used as control levels.

Convection

Heat transfer by actual movement in a gas or liquid promoted by differences in density at different temperatures.

Critical Temperature
The temperature above which a gas cannot be liquefied by compression.

Cryobiology
The branch of science dealing with the behavior of biological systems below ambient or physiological temperature, most especially at sub -freezing temperatures.

Cryoprotectant
A compound capable of preventing or reducing the damage to a formulated preparation during freezing, frozen storage, and thawing.

Crystal
A solid substance in which the atoms or molecules are arranged in an orderly geometric pattern in each of three dimensions.

D

D Value
The decimal reduction value refers to the time in minutes required under specified lethal conditions for a one-log or 90% reduction of a microbial population.

Defrosting
The removal of the ice from a condenser by melting or by mechanical means.

Degree of Crystallization
The volume or weight fraction of material converted to crystalline states, which for a eutectic solution or pure water is 1.0.

Degree of Supercooling
The number of degrees through which a system has been cooled below the equilibrium freezing point and remains liquid.

Dehydration
The removal of water from any substance.

Denature
Of soluble protein, to render it irreversibly insoluble.

Derivative
Anticipatory action that calculates the rate of change of the process and compensates to minimize overshoot and undershoot.

Desiccant
A drying agent.

Desorbing
The act of desorption.

Desorption
The release of liquids or gases trapped by sorption.

Diffusion
The motion of atoms and ions, or molecules or with respect to the another, in gases, liquids or solids

DIN
Deutsche Industrial Norms, a widely recognized German standard for engineering units.

Dry
Devoid of water.

Dry Cake
Dry layer. The partially or wholly dry porous mass of solute residue exposed as ice sublimes during freeze- drying.

Dry Weight
The weight of an absolutely dry substance.

Drying
The removal of moisture by any known means.

Duty Cycle
Percentage of "load on time" relative to total cycle time.

E

Edge of Failure
A control parameter value that, if exceeded, means adverse effect on state of control and/or fitness for use of the product.

End Point (of Primary Drying)
The instant when ice disappears completely from the product.

End Point (of the Freeze-Drying Process)
The point at which the product is sufficiently dry to render it acceptable.

Equilibrium Melting Point
The temperature at which the last ice crystal dissolves during the slow warming of a frozen aqueous system.

Ethylene Oxide (ETO)
A colorless, flammable, toxic gaseous or liquid compound, C2H40.

Eutectic Point
The lowest temperature in any system at which a residual liquid phase persists in equilibrium with respective solid phases.

Eutectic Temperature
A point in a phase diagram where three of more phases are present and the temperature and composition of the liquid phase cannot be altered without the disappearance of one of the solid phases.

Evaporation
The transformation from a solid or liquid to vapor or gas involving the escape of molecules from a surface.

Evaporative Cooling
Cooling of a substance resulting from the loss of the more energetic molecules.

Evaporative Freezing
Freezing of a liquid as a result of evaporative cooling.

Exothermic
Accompanied by the evolution of heat.

Expansion Tank
A tank located in the shelf heat transfer system used as a holding and expansion tank for the transfer fluid.

F

F Value
A physical parameter for the reference temperature used to predict the biological outcome of a process based on a straight-line, semi logarithmic microbial destruction model. When the reference temperature is 121.1°C provided via moist heat (saturated steam), the F value is referred to as Fo.

Filter or Filter/Drier
There are two systems that have their contents filtered or filter/dried. They are the shelf circulation fluid and the refrigeration system.

Free Water
Free water is that water that is more or less readily removed from the product in the context of a given drying operation. Typically, biological or chemical changes are minimized or stopped when free water is removed.

Freeze-Drying
(Lyophilization) Any process that involves the conversion of water to ice, the sublimation of the ice and further removal of some or all of any water not converted to ice, with the intent of rendering the product biologically and chemically inactive until reconstituted at some future date.

Freeze-Drying Cycle
A sequence of more or less well-defined steps that describes a succession of operations required during the freeze-drying of a product. Freeze-drying cycles most commonly state required shelf temperatures and system pressure and rates at which either or both should be changed.

Freeze-Drying Front
(Sublimation Interface) A term applied, where appropriate, to describe an evidently continues boundary between the frozen product and the cake freed from ice by sublimation.

Freeze-Drying Temperature
An expression that may refer to a temperature in a product or to the temperature of the shelf on which a product is being freeze-dried.

Freezing
Solidification, the process of changing from a liquid to a solid form, particularly from water to ice with the removal of heat. Freezing may involve a controlled change of the product temperature as a function of time to assure a completion of the process.

Freezing Point
The temperature at which liquid and solid crystalline forms of the same material are in equilibrium at standard atmospheric pressure.

Frozen
Reduced to a solid state.

G

Gas
A state of matter in which atoms and/or modules have free translational movement so that a gaseous substance completely fills a container irrespective of size.

Gas Ballast
Used in a vacuum system on the vacuum pump to remove small amounts of moisture in the vacuum pump oil.

Gas Ballasting
The admission of air to the interior of a rotary vacuum pump to reduce condensation of vapor in the oil.

Gas Bleed
To control the pressure in the chamber during the freeze-drying cycle to help the drying process, typically to improve heat transfer to the product.

Glass
Any physically solid amorphous, non-crystalline, material. Aqueous glasses may be formed during freezing and persist, with reduced water content, during and after freeze-drying.

Glass Transition Temperature
(Tg) The temperature at which an amorphous substance having viscoelastic properties is transformed into one with elastic solid properties or vice versa.

GMP

Good Manufacturing Practices. The Federal Drug Administration's guidelines for the pharmaceutical industry.

H

Heat

Transmissible energy, either as radiation or as thermal (i.e. kinetic) energy resident in a gas, liquid or solid.

Heat Exchanger

A mechanical device located in circulation and refrigeration systems that transfers heat from the circulation system to the refrigeration system. "Plate" type heat exchangers are most commonly used in freeze dryers.

Heat Transfer

The transfer of heat from a higher to a lower temperature, in a solid by conduction, in a fluid by conduction and convection, and through space by radiation. Heat may also be consumed by evaporation (or sublimation) and generated by condensation, as in a freeze-drying process.

Heat Transfer Fluid

A liquid of suitable properties for transferring heat to and from a component, for example, a shelf or condenser in a freeze dryer.

Heterogeneous

Having a large number of structural variations.

Homogenous

Having a single structural appearance with no variation.

Hot Gas Defrost

A function and use of a refrigeration system, employed, when desired, to defrost the condenser after a lyophilization cycle is complete.

Hydrophilic

Having an affinity for water.

Hydrophobic

Having a tendency to not wet, be wetted or dissolve in water.

Hysteresis

A difference in the response of a physical system to a change in constraint according to the polarity of the change.

I

Ice

A solid, crystalline form of water.

Inches of Vacuum

A scale in which atmospheric pressure is zero and a "perfect" vacuum is 30 inches (the height in a column of mercury supported by the vacuum).

Incipient Melting

A precursor to melting characterized by changes in the properties of a frozen system, e.g. by a relatively rapid reduction in the electrical resistivity of a frozen sample with increasing temperature.

Inert Gas

A chemically inactive gas, most particularly nitrogen or any of the "truly" inert gases (helium, neon and argon).

Insoluble

Unable to dissolve.

Installation Qualification

(IQ) Documented verification that all key aspects of the installation adhere to appropriate codes and approved design intentions.

Integral

Control action that automatically eliminates offset or "droop" between set point and actual process temperature. Also referred to as reset.

Interstage

In a two-stage compressor system, the crossover piping on compressors that connects the low side to the high side.

Interstage Pressure Regulating Valve

The valve that controls the Interstage pressure from exceeding 80 to 90 psi. This valve opens to suction as the Interstage pressure rises above 80 to 90 psi.

I/O

Input/Output.

Isolation

Separation. In electronics it is the electrical separation of a sensor from high voltage frequency. Allows for the application of grounded or ungrounded sensing element.

L

Latent Heat

The energy associated with a change of physical state under defined conditions.

LED

Light Emitting Diode.

Liquid

A state of matter intermediate between that of a solid and a gas in which molecules can move with respect to one another but form a virtually incompressible fluid that, under gravity, assumes the shape of a container vessel up to a definite level.

Liquid Sub-Cooler Heat Exchanger

A system in which the liquid refrigerant leaving the condenser/receiver is sub-cooled to a temperature of 15°F to -15°F (-10°C to -25°C).

Lyophilization

(Freeze-Drying) A process whereby a product is made to be chemically inactive by freezing, and then the solvents (primarily water) are removed via sublimation while the product is still in the frozen state and then by desorption, with the intent of creating a chemically inactive product that can be stored at temperatures close to room temperature or substantially above the product's original freezing point.

Lyoprotectant

A substance included in a formulated product to prevent or reduce damage to an active ingredient during freeze-drying.

M

Manifold Freeze-Drying

Drying in containers attached to a manifold such that the product receives heat from the room.

Manometric Temperature Measurement

(MTM) A procedure to measure the product temperature at the sublimation interface during primary drying by quickly isolating the freeze-drying chamber from the condenser for a short time and by subsequent analysis of the pressure rise during this period. Allows the computation of the resistivity of the freeze-dried section of the cake.

Mass

The amount of matter in a body.

Matrix

A frozen matrix: A system of ice crystal (the ice phase) and other solids that characterized the frozen product. A freeze-dried matrix: a cake structure created by and retained after freeze-drying.

Mean Free Path

The average distance a molecule can travel as a gas before it collides with another molecule.

Mechanical Vacuum Pump

The mechanical system most often employed to lower the pressure in the chamber to facilitate freeze—drying.

Melt Back

One of a number of terms traditionally employed to describe "collapse" or a collapsed product.

Melting

The process of changing from a solid to a liquid.

Melting Point

The temperature at which a crystalline solid and a liquid can exist in equilibrium at standard atmospheric pressure. The temperature at which a solid changes into a liquid.

Melting Temperature

The temperature where mobile water first becomes evident in a frozen system (either by casual observation or by instrumental determination).

Microbar

A unit of pressure used in the freeze-drying or lyophilization process. One microbar (a pressure of one millionth of a bar) equals 0.75 millitorr.

Micron

(See Torr). A unit of pressure used in the freeze-drying/lyophilization process. One micron (the pressure that supports a column of mercury to one millionth of a meter high) is also equal to 1.33 microbar.

N

N.I.S.T

National Institute of Standards and Technology. A US agency, formerly the National Bureau of Standards (NBS).

Non-Aqueous Freeze Drying

Any freeze-drying process in which the solvent or solvent system contains no water, but in which the solvent can be crystallized by cooling and vacuum allows sublimation.

Non-Condensable

Gases such as hydrogen, helium, neon, nitrogen, oxygen and argon. They may be drawn into a vacuum system through leaks. Their presence may reduce the operating efficiency of the freeze dryer.

NPT

National Pipe Thread. May be FNPT for female national pipe thread or MNPT for male national pipe thread.

Nucleation

The initiation of the crystallization process. Nucleation may be heterogeneous or homogenous.

O

Oil Mist Filter

(Oil Mist Eliminator). A filter attached to the discharge port of an oil-sealed rotary vane pump to eliminate most of the aerosol and often times, return it to the pump.

Oil Sealed Rotary Vane Vacuum Pump

A standard type of mechanical vacuum pump used in a majority of freeze-drying applications.

Oil Separator

Separates the oil from the compressor discharge gas and returns the oil through the oil float trap and piping to the compressor crankcase.

On/Off Control

Control of temperature about a set point by turning the output full on below set point and full off above set point in the heat mode (and vice versa in the cooling mode).

Operating Variables

All factors, including control parameters that may potentially affect process state of control and/or fitness for use of the end product.

Operational Qualification

(OQ) Documented verification that the system or subsystem performs as intended through all anticipated operating ranges.

Overshoot

Condition where temperature exceeds set point due to initial power up or process changes.

P

Parenteral Drug

Injected, infused or implanted medicinal product.

Part Aqueous Freeze-Drying

Any freeze-drying or lyophilization in which the solvent system is partly aqueous (i.e. contains water, among other solvents).

Partial Pressure

In a mixture of gases or vapors or both, the pressure exerted by any one of the species independently of the others.

Phase Diagram

A graphical representation that describes the physical state of a system as a function of composition and temperature.

Phase Transition

A change of physical state which can include i.e. crystallization, melting and dissolution (each of which is called a first order transition). Second order phase transitions include glass transitions (conversions from i.e. brittle to elastic amorphous states to viscous fluid states).

PID

Proportional Integral Derivative. Type of control incorporating the three control strategies.

Pirani Gauge

An instrument, named after the inventor, for measuring total gas pressure in a vacuum system in which the temperature of a heated filament (or the power to heat the filament) allows the quantification of the pressure. Commonly used in freeze dryers but provides erroneously high readings in the presence of water.

Pressure

Force per unit area.

Primary Drying

That part of the freeze-drying process that involves the sublimation of ice or that part of the freeze-drying process allocated to the sublimation of ice.

Process Analytical Technology

(PAT) A mechanism to design, analyze, and control pharmaceutical manufacturing processes through the measurement of critical process parameters.

Process Development

Establishing evidence that all process control parameters and all control parameter ranges are validated and optimized.

Process Validation

The documentation of evidence that a process does what it purports to do.

Process Variable

A system element to be regulated, such as time, temperature, pressure, relative humidity.

Product

Material prepared for freezing and/or freeze-drying or the same material after freezing and freeze-drying.

Proportional Band

Span of temperature about the set point where time proportional control action takes place.

Prospective Validation

Establishing documented evidence that a system does what is purports to do based on a preplanned protocol.

Protocol Supplement

A document that explains a change to the original protocol, including reasons for its need.

Proven Acceptable Range

(PAR) All values of a given control parameter that fall between proven high and low worst-case conditions.

PSI

Pounds per Square Inch.

Puffing

One of a number of terms applied to describe freeze-drying in which product exhibits a gross expansion as it freeze-dry's, generally at too high a freeze-drying temperature and more specifically above a threshold collapse temperature).

Q

Qualification Process Validation

Establishing documented evidence that a process does what it purports to do based on information generated during actual implementation of the process.

Quality Assurance

The activity of providing, to all concerned, the evidence needed to establish confidence that the qualify function is being performed adequately.

Quality Control

The regulatory process through which industry measures actual quality performance, compares it with standards and acts on the difference.

Quality Function

The entire collection of activities from which the industry achieves fitness for use, no matter where these activities are performed.

R

Radiation

Heat transferred through space, generally by infrared or by visible light.

Real Leak

A movement of atmospheric gases that results from a penetration through an opening (an actual hole) in a freeze dryer wall.

Reconstitution

Restoration of a dried substance to its former wet condition by the addition of the original solvent (generally pure water).

Recrystallization

Most frequently the growth of larger crystals at the expense of smaller ones i.e. a grain growth or ripening generally of ice, but a term to be examined and used with caution in any case.

Relieve Valve

Used for safety purposes to prevent damage in case excessive pressure is developed.

Resistivity

Specific electrical resistance. The resistance, in ohms, of a unit cube of a given material, measured between and across opposing faces.

Resistivity Measurement

(Resistance Measurement) Measurement of changes in the resistivity (or ohmic resistance) of a sample subjected to cooling and warming (i.e. during freezing and thawing), all with a view to the prediction (and possible control) of freeze-drying behavior. Once generally measure actual ohmic resistance and derives resistivity by calculation.

Retention

A term signifying the persistence of structure in the dry cake as opposed to its loss (see "Collapse").

Retrospective Validation

Establishing documented evidence that a system does what it purports to do based on review and analysis of historic information.

Revalidation

Repetition of the validation or a specific portion of it.

Rotary Vane Pump

A mechanical pumping system with sliding vanes as the mechanical seal. Such a pump is typically two stage for freeze dryers.

RTD

(Resistant Temperature Detector) A transducer whose resistance change corresponds to temperature.

S

Saturated Solution

A solution in thermodynamic equilibrium with excess (crystalline) solute.

Scroll Vacuum Pump

(Dry Pump) A vacuum pump utilizing scroll compressor technology thereby not requiring a fluid such a vacuum pump oil in an effort to create vacuum. These pumps are typically more expensive that oil sealed rotary vane vacuum pumps but in some applications are required to ensure the highest level of cleanliness in a freeze dryer.

Secondary Drying

That part of the freeze-drying process that follows primary drying and is conventionally regarded as the second stage and a time for continuing solvent desorption.

Sensible Heat

Perceptible heat associated with temperature, since the heat content of a given mass of a substance in a given state varies with temperature.

Septic

An object or material that is free of organisms which may cause specific damage or infection.

Shelf Life

The length of time, depending on its stability, for which an object can be stored under given ambient conditions before its latent characteristic properties fall below a defined level.

Shell Freezing

A freezing process that forms a hollow frozen shell from liquid in a cylindrical or spherical container. The operation requires a slow rotation about a nearly horizontal axis and a partial or total immersion in a refrigerated fluid. May be done by hand or in a shell freezer.

Shelves

Freeze dryer shelves serve to support the product and (most frequently) to freeze and/or keep it frozen, then to furnish heat to facilitate the freeze-drying process. A circulating fluid follows a serpentine path within each shelf, entering on one side and leaving on the other. Shelves may be movable for stoppering or fixed where stoppering is not required.

Shrinkage

Reduction in the size of the dry cake.

Silicon Oil

An often-used fluid for circulating heat transfer in freeze dryers.

Skin

A relatively impermeable layer found on the upper surface of some freeze-dried cakes formed, apparently by the freeze-drying of a locally concentrated solution and promoted by freezing from below.

Soluble

Able to dissolve, especially in water.

Solute

A substance capable of dissolving, especially in water.

Sorption

The physical or physico-chemical retention of one substance by another, generally of a smaller quantity of a "sorbate" by a larger quantity of a "sorbent".

Specific Heat

The heat capacity of a substance compared with water in, most commonly, calories per gram or BTU per pound.

State of Control

A condition in which all operating variable that can affect performance remain within such ranges that the system or process performs consistently and as intended.

Sterility Filter

A bacteriological filter fitted closely over the opening of a product container in freeze-drying.

Sterilization

The removal or destruction of all living organisms from an object or material.

Sterilization Process

A treatment process from which probability of any microorganism survival is less than ten or one in a million.

Sublimation

The conversion of a material from a solid crystalline phase directly to a vapor phase, without passage through the liquid phase.

Sub-Cooled Liquid

The liquid refrigerant is cooled through an exchanger so that it increases the refrigeration effect as well as reduces the volume of gas flashed from the liquid refrigerant in passage through the expansion valve.

Suction Line Accumulator

A device that provides adequate refrigerant liquid slug protection (droplets of liquid refrigerant) from returning to the compressor and causing damage to the compressor.

Supercooling

(Subcooling, Undercooling) The persistence of a liquid state below and equilibrium freezing point.

Supersaturation

The persistence of a solution at a concentration higher than that of the corresponding saturated solution.

T

TDLAS

Tunable Diode Laser Absorption Spectroscopy. Utilized to determine the temperature, pressure, velocity and mass flux of the gas under observation.

Temperature

The degree of hotness or coldness of a body.

Thermal Treatment

(Annealing, Tempering) The controlled and generally limited warming of frozen system with a view to further development of an ice phase and/or the crystallization of one or more other components capable of eutectic behavior.

Thermocouple

A temperature sensing device that is constructed of two dissimilar metals wherein a measurable, predictable voltage is generated corresponding to temperature.

Thermocouple Vacuum Gauge

An instrument for measuring total pressure in a vacuum system in which variations in the temperature of a heated filament are quantified by a thermocouple. Erroneously high-pressure readings occur in the presence of water vapor.

Thermostatic Expansion Valve

An automatic variable device controlling the flow of liquid refrigerant.

Thief

(Product Thief, Sample Thief) A device for removing vials from the freeze dryer through a vacuum lock, without interrupting the process, in order to carry out a check on residual moisture.

Time Proportioning Control

Action that varies the amount of 'on' and 'off' time when close to the set point, i.e. the proportional band. The variance is proportional to the difference between the set point and the actually process temperature. In other words, the amount of time the output relay is energized depends on the system temperature.

Torr

A unit of pressure measurement equivalent to 1 mm of mercury or 1000 microns of mercury.

Triple Point

A state in which three phases of the same substance (crystalline solid, liquid and vapor) coexist in thermodynamic equilibrium.

Two Stage Compressor

This is a specially built compressor. Its function is to be able to attain low temperatures by being able to operate at low pressures. It is two compressors built into one. A low stage connected internally, and a high state connected externally with piping, called interstage.

U

Ultimate Vacuum

The vacuum (lowest pressure) that a particular vacuum pump can achieve in a clean, dry leak-free system.

V

Vacuum

Strictly speaking, a space in which the total pressure is less than atmospheric.

Vacuum Break

A special VBS vacuum solenoid designed to isolate the vacuum pump from the condenser and product chamber during power failure.

Vacuum Break Valve

A valve for the admission of gas for breaking vacuum.

Vacuum Control

(Gas Bleed) Control of pressure in the freeze-drying chamber to provide the most favorable balance between heat and vapor transfer to and within the product to achieve a minimum primary drying time consistent with the maintenance of product quality.

Vacuum Pump

A mechanical means of reducing the pressure in a vessel below atmospheric to facilitate sublimation. There are various types of vacuum pumps including oil sealed rotary vane, dry pumps, rotary piston and mechanical booster pumps.

Vacuum Valve

Vacuum valves close without leaking and may be of ball or disk (butterfly) or other design.

Validation

Establishing documented evidence that a system does what it purports to do.

Validation Change Control

A formal monitoring system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect validated status and cause corrective action to be taken that will ensure that the system retains its validated state of control.

Validation Guide

A validation guide and workbook consisting of a series of FDA required lyophilizer performance tests and audit reports.

Validation Protocol

A prospective experimental plan that, when executed, is intended to produce documented evidence that the system has been validated.

Validation Task Report

A scientific report of the results derived from executing a validation protocol.

Validation Task Report Conclusions

A brief summary of conclusions from a specific task report, usually indicating validation success and designating proven acceptable ranges that have resulted. The conclusions are formally approved.

Vapor Baffle

An object placed in the condenser to direct vapor flow and to promote an even distribution of condensate.

Vapor Valve

(Isolation Valve) The vacuum valve between the chamber and the external condenser. When this valve is closed the chamber is isolated from the external condenser.

VHP

Vaporized Hydrogen Peroxide. May be utilized as a chemical sterility in freeze dryers or as a vehicle for other chemical sterility.

Vial

(Serum Bottle, Serum Vial) In freeze-drying, small glass bottles with a flat bottom, short neck and flat flange designed for in-situ stoppering. Vials may be molded or tube drawn.

Virtual Leak

In the vacuum system a virtual leak is the passage of gas into the chamber from a source located within the chamber itself.

Volatile

Having a strong tendency to evaporate at room temperature. Having a high vapor pressure.

W

Warming

Raising the temperature in any part of the temperature scale.

WFI

Water for Injection. This water is required for preparing parenteral solutions and manufacturing drug products.

SP

935 Mearns Road, Warminster, PA 18974 USA | scientificproducts.com
+1-800.523.2327 | hello@spindustries.com