

glossary of formulation, production, and packaging terms

A

Abbreviated new drug application (ANDA). A request submitted to the FDA for approval of a generic drug product. It is usually not required to include preclinical and clinical data to establish safety and effectiveness. Instead, a generic drug applicant must scientifically demonstrate that its product is bioequivalent.

Active pharmaceutical ingredient (API). A substance or mixture of substances used in the manufacture of a drug product that provides the pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or affects the structure or function of the body.

Adhesion. A molecular attraction between different materials, such as a metal surface and powder.

Agglomerate. *Noun.* The product of size enlargement, such as a granule. A group of particles held together at their points of contact by solid bridges. *Verb.* The process of forming fine particles into permanent larger shapes in which individual particles can still be distinguished.

Aggregate. A group of particles held together by weak electrostatic and Van der Waals forces.

Agitation. A type of particle size enlargement without the use of pressure, either by tumbling, coalescence, or particle growth.

Air vents. Channels located at the cut-edge of a capsule body that allow air to escape during capsule closing.

Assay. A laboratory test that identifies or measures the amount of a substance in a sample and helps determine its characteristics, such as potency and/or purity.

Atomization. The process of creating a fine, controlled mist by passing air and a solution through a nozzle; used for film coating, wet granulation, and spray drying.

Attrition. The process of tumbling an agglomerate to determine its resistance to surface abrasion.

B

Balcony-style design. A cantilever configuration of machines, such as blister packaging equipment, that facilitates access for changeover, cleaning, and maintenance.

Band. The area between opposing tablet cup profiles that is formed by the wall of a tablet die; also a liquid seal that is applied around the joint of filled two-piece capsules.

Banding. The process of applying a band around the joint of two-piece capsules filled with powders or liquids to provide tamper evidence and to prevent leakage.

Bar code. A way of labeling a product with a description and batch information using a series of lines of varying thicknesses that is read by a scanner. It comes in multiple formats, including 2-D matrix codes.

Barrier. Used to describe packaging material properties that prevent moisture and/or oxygen from coming into contact with products.

Batch operation. A method by which one lot of a formulation is processed at a time, in contrast to continuous operation.

Bi-layer tablet. A tablet comprising two distinct layers.

Binder. An excipient used to increase powder cohesiveness, which increases the bonding strength of the final product. In wet granulation, they help form agglomerates.

Bioavailability. A measure of the uptake of an API by the body, including the rate at which and extent to which it is absorbed or is available at the treatment site.

Bioequivalence. The absence of a significant difference in the rate and extent to which an API becomes available at the site of action when two different drug products are administered at the same dose under similar conditions. The basis by which generic drug products are approved by comparing them to the brand-name product.

Biopharmaceutics Classification System (BCS). A four-quadrant system of classifying the solubility and absorption rate characteristics of a drug substance.

Bisect/score. A groove or debossed line in the tablet surface that controls stress fracturing. It also allows the tablet to be split into pieces for partial dosages.

Blister. A cavity formed in film or foil by heat and/or mechanical means.

Blister pack. A package that comprises one or more blisters filled with tablets or capsules and sealed with film or foil lidstock.

Body. The lower part of a two-piece capsule. It is slightly smaller in diameter and longer than the cap.

Body fold. An imperfection in the capsule body caused by depositing material on it during filling.

Bonding. The force of cohesion between particles.

Bottle. A glass or plastic container used to package solid or liquid drug products or dietary supplements.

Bovine. Originating from cattle; used to describe gelatin made from cattle products.

Brittleness. The extent to which a material will break without undergoing significant elastic or plastic deformation. Brittle materials are desirable in tableting since brittle fracture is in the main independent of machine speed and provides fresh surfaces for bonding after consolidation.

Bulk density. The mass per unit volume of a material under specified conditions of pressure.

C

Calendar blister. A blister pack that shows the day and time that each dose is to be taken to help the patient comply with the physician's dosing instructions. The information can be on the blister pack or on the packaging surrounding it.

Calibration. To standardize flow or batch measurement by correcting for deviation from a standard. Also to determine, by measuring or comparing with a standard, the correct value of each scale reading on a meter or other device or the correct value for each setting of a control knob.

Cap. The upper part of a two-piece capsule. It is slightly larger in diameter and shorter than the body.

Caplet. A tablet shaped like a capsule to ease swallowing.

Capping. Fractures that occur between the tablet cup and the band due to poor particle adhesion, overcompression, and/or insufficient air release during compaction.

Capsule filler. A machine that fills two-piece capsules with a pharmaceutical or dietary-supplement formulation. Also known as an encapsulation machine.

Capsule filling. The process of filling a two-piece capsule with a pharmaceutical or dietary-supplement formulation. Also known as encapsulation.

Carton. A sealed paperboard box that contains a blister pack and product information.

Certification. A quality management process based on requirements mandated by international standards organizations.

Changeover. The process of changing production from one product to another. This often includes clearing the production area of supplies and components, changing size-specific machine parts, and cleaning the production area and equipment to eliminate cross-contamination.

Child-resistant. Used to describe packaging that passes a test protocol required by the US Consumer Product Safety Commission to increase child safety.

Clean-in-place (CIP). A method of cleansing all contaminants from the interior surfaces of process equipment without disassembling it.

Cleanroom. An enclosed space that is environmentally controlled with respect to the size and count of airborne particles, temperature, humidity, lighting, air pressure, airflow patterns, and air motion.

Clinical trials. Investigations in humans to prove the safety and efficacy of new drug products in order to gain market approval. The investigation of a previously untested drug is usually divided into Phase I, II, III, and IV studies.

Coacervation. The process of transforming a dissolved colloidal polymer into a solid precipitate.

Coagulation. The process of converting a solution to a gel in conjunction with precipitation.

Coalescence. The process of joining drops of an emulsion to form a compact liquid phase.

Coating. The process of applying a layer of material, film, or finish to a tablet, capsule, or substrate.

Coating pan. A bulbous, conical, or cylindrical mixing vessel in which a material layer or film coating is applied to particles, granules, tablets, or capsules, usually involving liquid and heat.

Coating solution. Powders suspended in an aqueous or solvent solution; used as a carrier for film coating or wet granulation.

Cohesion. A molecular attraction between like substances or between molecules of the same substance.

Colloids. The smallest particles in a liquid or solid phase.

Compaction. The process of compressing and consolidating powders into a tablet, slug, or other form.

Compliance. Adhering to a prescribed regimen by taking medication correctly, or adhering to a regulatory mandate. Also known as adherence.

Compression. The process of reducing the bulk volume of a material by applying an external force.

Consolidation. The process of increasing the mechanical strength of a material due to particle-particle interaction, often as a result of an applied external force.

Containment. The act of confining within a defined space a microbiological agent, potent or toxic API, or other entity that is being cultured, stored, manipulated, or transported to prevent or limit its contact with people and the environment.

Continuous operation. A method or process that is repetitive, operating over long periods without interruption, and in which materials are processed without segregation.

Controlled release. A method of drug delivery by which API release is predominantly controlled by the design of the delivery system and mostly independent of external factors.

Core. An uncoated tablet. Also the tablet around which a second tablet is formed in tablet-in-tablet compositions, known as compression coating.

D

De-agglomerate. The process of separating adhered granules into individual granules or smaller groups of granules without reducing them to their constituent powders.

Debossing. Tablet identification formed as a groove or indentation in the tablet's surface.

Deduster. A piece of equipment that removes flashing and dust from solid dosage forms. It is often combined with a metal detector and installed at the outlet of a tablet press or capsule filler.

Delivery platform. A series or collection of proprietary methods, processes, or materials that facilitates the formulation of drug products and dietary supplements.

Dented end. A dimple-like imperfection in the dome area of a capsule cap or body.

Desiccant. A highly hygroscopic substance used to absorb moisture in bottles, vials, blisters, and other packaging.

Dial pack. A package that must be turned at a specific interval to remove a dose. Commonly used for oral contraceptives.

Die. A circular machine tool with a central cavity in which powders or granular solids are compacted into tablet form between the upper and lower punches of a tablet press.

Dietary ingredient. A substance or mixture of substances used in the manufacture of dietary supplements that may or may not address a dietary deficiency. Substances may be extracts or concentrates and include vitamins, minerals, amino acids, and herbs, among others.

Dietary supplement. A solid dosage form that contains a substance or mixture of substances that may or may not address a dietary deficiency. Also known as a nutraceutical.

Direct-heat drying. A method by which hot gas directly contacts the wet material, causes evaporation, and carries off the vapor. Examples include fluidized beds, pneumatic conveyors, and rotary or spray dryers.

Disintegration. The breakup of a tablet into fine particles—usually less than 2 millimeters in diameter—in water, simulated gastric fluid, or simulated intestinal fluid at body temperature.

Dissolution test. A process by which a known amount of API in a dosage form dissolves in unit time under standardized conditions of liquid-solid interface, temperature, and media composition. In cases where an *in vitro*-*in vivo* correlation is established, it may measure bioequivalence.

Dosage form. The physical form in which a drug product or dietary supplement is produced and dispensed, such as a tablet or a capsule.

Dosage strength. The amount of API present in each dosage form, usually measured in milligrams.

Dose. The prescribed amount of medication to be taken.

Draft guidance. Potential guidelines published by the FDA for public comment that represent its current thinking on an industry topic. Final guidelines may be issued by the FDA after it takes the public's comments into consideration.

Dry granulation. The process of densifying powders to form granules. It is accomplished by making compacts using roller compaction or a tablet press and then milling them to produce granules of the appropriate size.

E

Edge chipping. The loss of particles from the juncture of the tablet band and cups during coating or packaging.

Elasticity. The extent to which a material will deform and still be able to return to its original shape—an undesired material property in tablet ingredients.

Embossing. Tablet identification that protrudes above the tablet's surface or punch cup.

Encapsulation. The process of enclosing powders, small granules, pastes, semi-solids, or liquids in a protective membrane or capsule.

Excipient. An inactive ingredient added to an API during product manufacturing. They are often classed as diluents, binders, flow aids, disintegrants, colorants, or lubricants and can act to improve bioavailability and stability, control drug release, add flavor, or mask off-tastes.

F

Fatigue analysis. A computerized method for determining tool life based on a variety of compacting force conditions.

Feeder. A device located beneath a tablet press hopper that directs material into the dies, known as a powder feeder, mechanical feeder, induced-die feeder, or feed frame. Also a device that meters bulk material according to gravity, mass, or volume.

Finite element analysis (FEA). A computer-based method of determining stresses and deformations in tablet tools of complex shapes. The technique identifies the weak areas on a punch cup before tablets are produced and enables the designer to make the tools stronger.

Flashing. Small extrusions that appear around the tablet's periphery where the band meets the cups. It usually flakes off during handling, dedusting, or coating.

Flowability. A measure or characterization of how well powders, granules, and other bulk solids flow.

Fluid-bed dryer. A device that dries powder using mechanical force and/or airflow to elevate and aerate it, increasing interstitial particle spacing and driving off moisture.

Fluid-bed granulation. The process of spraying solution onto aerated powders to form granules.

Fluidization. The process of suspending powders or other materials via mechanical force and/or airflow, usually in drying, granulating, or coating operations. The term derives from the fluid-like behavior of the suspended powders.

Foil. Thin-gauge aluminum, usually 20 to 25 microns thick, that can be used as blister material, push-through lidstock, or backing when combined with film or paper. It is available with a hard or soft temper and can be printed on two sides and in multiple colors.

Friability. The degree to which particles become detached from an agglomerate. Tablets are often subject to this type of test.

G

Gelatin. A translucent, colorless, nearly tasteless solid substance that is extracted from the collagen found in animals' connective tissue. It is commonly used to make softgels and the shell of two-piece capsules.

Gelcap. A gelatin-coated tablet that is tamper-evident and easy to swallow.

Generally recognized as safe (GRAS). A designation given to a substance that is considered safe by the FDA to add to food and is thus exempted from the Federal Food, Drug, and Cosmetic Act food-additive tolerance requirements.

Generic. A copy of a prescription or OTC drug product that does not have patent protection.

Good manufacturing practice (GMP). Principles and procedures that specify that the design, operation, practice, and sanitization involved in solid dosage manufacturing comply with quality standards.

Granulation. The process of adhering particles together to form granules.

Granule. Particles of powder bonded together.

Gravimetric feeding. The process of metering material according to mass, which is determined by a weighing device.

Guidance. Final guidelines issued by the FDA that represents its current thinking on an industry topic. The guidelines are developed in response to comments and questions the FDA received regarding the topic, usually after having issued a draft guidance.

H

Harmonization. A project that brings together the regulatory authorities of Europe, Japan, and the US and experts from the pharmaceutical industry in these regions to achieve greater agreement and uniformity in the interpretation and application of technical guidelines and requirements of pharmaceutical practices. Goals include the reduction or elimination of duplicate tests and certifications during research, development, and manufacture.

Hot melt extrusion (HME). The creation of a solid solution in which the API is dissolved in thermoplastic excipients using a screw extruder.

Hygroscopicity. A material's ability to absorb moisture from its surroundings.

I

Immediate release. A method of drug delivery in which the tablet or capsule dissolves in the gastrointestinal tract without delay, allowing fast uptake of the API.

Induction sealing. A non-contact method of heating a foil liner or inner-seal to hermetically seal the top of filled and capped plastic or glass bottles. Also known as cap sealing.

Inline or online analysis. Analysis of a sample conducted without interrupting a process that usually allows quick, real-time adjustments to be made to the process.

Installation qualification (IQ). Validation documentation that shows equipment has been installed properly.

Intrinsic dissolution. Determination of a mass dissolved in a system with contact surface area. Usually expressed in terms of milligram per unit of time per cubic centimeter.

Investigational new drug application (INDA). A request submitted to the FDA that must be approved before clinical trials of a new drug begin. It must contain a full description of the new drug, including the structural formula, animal-test results, and manufacturing information.

In vitro-in vivo correlation. A predictive mathematical model describing the relationship between the biological and physicochemical properties of a dosage form.

L

Laminating. An imperfection caused by parts of a tablet separating in the band area or where the cups meet the band.

Leaker. A liquid-filled two-piece capsule or softgel that leaks its contents.

Lidstock. Material used to seal blisters to prevent or minimize moisture and/or gas permeation.

Locking ring. A mechanical fit of a capsule cap and body that secures filled two-piece capsules after closing.

Loss-in-weight feeding. The process of gravimetrically metering material by measuring the weight loss from a hopper.

Lot number. A number assigned to a production batch or segment that allows all of the product's components to be traced.

Lubricant. A mold release agent blended into powders to prevent them from sticking to a tablet punch and dies. Magnesium stearate is the most common agent.

M

Marine. Originating from the sea; used to describe gelatin made from fish products.

Micro-encapsulation. The process of enveloping one substance with another on an extremely small scale. The core substance can be a solid or a liquid, and the enrobing substance is a film-forming polymer. It is often used for controlled-release formulations.

Micronization. The process of reducing the particle size of powders to the single to tens of micrometers.

Milling. The process of de-agglomerating or reducing the particle size of powders manually or by machine.

Moisture vapor transmission rate (MVTR). The amount of humidity that passes through packaging film or foil over a unit of time and under specific environmental conditions.

Monograph. Published, official standards in a national pharmacopoeia that define the testing requirements and acceptance criteria of pharmaceutical and other substances or preparations.

Mouth-feel. A complex sensory impression obtained from the lips, teeth, tongue, and oral cavity when ingesting drugs or food. The sensory aspects are based on elasticity, taste, viscosity, and other properties of the drug or food.

Multi-layer tableting. The process of manufacturing tablets that comprise two or more distinct layers.

N

Neat API. An API that is not combined with excipients, usually used in clinical trial materials.

New drug application (NDA). A request submitted to the FDA for approval after clinical trials have been completed. It must contain data from chemistry, pharmacology, medical, biopharmaceutical, and statistical points of view. If the FDA grants approval, the product may be marketed in the US.

Non-compliance. Failure to take medication as prescribed, to follow a prescribed course of therapy, or to adhere to a regulatory mandate.

O

Occupational exposure limit (OEL). The upper level of the acceptable concentration of a hazardous substance in workplace air for a particular material or class of materials. The levels are usually set by national authorities and enforced by legislation.

Offline analysis. Analysis of a material sample removed from a process and taken to the analyzer. Results determine what adjustments, if any, should be made to the process.

Operational qualification (OQ). Validation documentation that shows equipment functions according to specifications in the selected environment.

Orally disintegrating tablet (ODT). A drug delivery system that dissolves in seconds when placed on the tongue. The system can be taken without water and improves compliance when patients have difficulty swallowing.

Orange peel. An imperfection in the coating of a tablet so named because of its resemblance to the fruit, usually caused by using too much atomizing air.

Original pack dispensing (OPD). The act of giving pharmaceutical products to patients without any change to their trade dress.

Overcompression. The act of applying excessive compaction force to a tablet, often resulting in defects.

Overencapsulation. The process of placing a tablet or capsule within a capsule. An opaque capsule is often used to conceal an investigational drug during clinical trials so that neither the investigators nor subjects can identify the medication from the placebo or comparator they are administering or ingesting.

Overload. A device on a tablet press that protects the tooling from too much pressure.

Over-the-counter drug (OTC). A drug product that is safe and effective for use without a prescription.

Oxygen transmission rate (OTR). The amount of oxygen that passes through packaging film or foil over a unit of time and under specific environmental conditions.

P

Particle analysis. The process of examining a particle or group of particles to determine their size, shape, or other characteristics. It is usually conducted on a sample rather than the whole bulk of material.

Particle engineering. The process of changing the morphology and/or other physico-chemical properties of a powder, such as by spray drying, hot melt extrusion, or the creation of micro- or nano-particles, usually for the purposes of improving solution rate or solubility for better bioavailability.

Particle size distribution. The relative amount of particles present according to spherical diameter, mass, or other unit of measure.

Peeling. An imperfection in which a film coating flakes off the tablet core, often because of poor surface tension.

Performance qualification (PQ). Validation documentation that shows equipment consistently produces products that meet predetermined specifications and have suitable quality attributes.

Permeability. The degree to which film or foil allows dissolved substances to pass through; used to describe moisture or oxygen transmission.

Phase I. Clinical trial studies in which a new drug product or treatment is administered to a small group of patients or healthy volunteers to evaluate its safety, determine a safe dosage range, and identify any side effects.

Phase II. Clinical trial studies in which a new drug product or treatment is administered to a larger group of patients with the disease or condition for which treatment is sought to gauge its effectiveness and to further evaluate its safety.

Phase III. Clinical trial studies in which a new drug product or treatment is administered to larger groups of patients to confirm its effectiveness, monitor its side effects, compare it to commonly used treatments, and collect information showing that the new drug product or treatment can be used safely. When this phase is complete, a request for marketing approval can be submitted to the FDA.

Phase IV. Human studies performed after the drug product or treatment has been marketed. These studies can be used to gather more information on the drug's effect on various populations, to detect any side effects associated with its long-term use, or to identify additional uses.

Physical-chemical identifiers (PCIDs). Inactive ingredients that are added to solid dosage forms and/or packaging and that can be detected and authenticated to deter counterfeiting. Ingredients include inks, molecular taggants, pigments, and flavors.

Picking. An imperfection caused by powders sticking to a punch surface during tableting, often resulting in voids where letters and numbers with islands (enclosed areas)—such as A, O, P, 6, and 8—used to be.

Plasticity. The extent to which a material will deform permanently without breaking. Plastic flow is time-dependent and is usually preceded by elastic deformation. Highly plastic materials in tableting may demonstrate tablet properties dependent on machine speed.

Porcine. Originating from pigs; used to describe gelatin made from pig products.

Pouch. A flexible package for medications.

Pre-lock. Small indentations around the perimeter of a capsule cap that keep empty two-piece capsules in a semi-closed position until the capsule filler separates the capsules.

Prescription drug. A drug that requires a written order by a medical physician or veterinarian to a pharmacist before dispensation or sale.

Process analytical technology (PAT). A system for designing, analyzing, and controlling manufacturing through timely measurements of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality.

Punch cup. The depression, or concavity, of the punch tip. It forms the tablet face.

Punch tip edge. The cup-edge that adds to the overall length of a punch. The weakest area of the punch tip to sustain the force of compression.

Punch-to-die clearance. The gap between the punch and die. It is determined by subtracting the diameter of the punch tip from the minimum internal diameter of the die cavity.

Q

Quality assurance (QA). Procedures established to ensure a clinical trial or manufacturing process is properly documented and meets standards and regulatory requirements.

Quality control (QC). Regulatory inspection and analysis to check performance, compare it with standards, and adjust the process to ensure that specifications are met.

R

Radio frequency identification (RFID). A technology that uses tags to emit data as radio signals and transmit them to a reader. It is an alternative to bar coding and does not require direct contact or line-of-sight scanning.

Relieved area. A purposely weakened area of a package that makes it easy to open.

Roller compaction. The process of densifying dry powders by compressing them between rolls, usually used to achieve more uniform distribution of a formulation's ingredients.

Roller compactor. A device that compresses dry powders.

S

Sample. A representative portion of a bulk material.

Scale-up. The process of converting a small-volume process to large-volume production.

Screening. The process of reducing agglomerates, sorting particles by size, and removing oversized particles and contaminants using a woven metal screen or perforated plate.

Senior-friendly. Used to describe packaging that is easy for elderly patients to read, handle, and open. It is a measured part of the Consumer Product Safety Commission's child-resistant protocol.

Shingle. An effect caused by tablets stacking or backing up on the die table during ejection instead of them pushing each other off the tablet press.

Sieving. Used for particle size and size-distribution analysis, the method uses one or more shallow, round pans that have mesh openings or perforations of a known size at their base. The pans are stacked so that the smallest openings are at the bottom. A weighed sample is fed into the top sieve, vibrated or tapped, and then the material remaining on each sieve is weighed to determine the particle size distribution.

Slug. A large compact made in a specialized tablet press for the purpose of dry granulation.

Softgel. A one-piece capsule made from gelatin or suitable polymer, such as modified starch, usually filled with liquid formulations.

Softgel encapsulation. The process of forming and filling softgels with pharmaceutical or dietary-supplement formulations.

Solid dosage form. A non-liquid dose that includes tablets and capsules, including liquid-filled capsules.

Split. A defect caused by a misjoined capsule cap and body, which usually results in leakage.

Spray drying. The process of forming fine, granular solids or bead-like agglomerates by spraying a liquid or semi-liquid suspension or slurry into the top of a tall chamber in the presence of drying gases to evaporate the moisture.

Stability testing. A technique for determining how drug products degrade when stored at different humidities and temperatures.

Sticking. The adhesion of powders to a punch surface during tableting.

Strip pack. An inexpensive package for individual solid dosage forms.

Surface abrasion. The loss of powder particles from a tablet surface due to attrition during transfer and handling after compression.

Surfactant. A substance that decreases the surface tension of a liquid. When used above the critical micelle concentration, it can increase drug solubility.

Sustained release. A method of drug delivery by which API release occurs over an extended period after administration. The method reduces the dosing frequency compared to a traditional method, such as immediate release.

T

Tablet. A compacted, molded formulation in its final dosage form.

Tablet breaking force. The pressure that causes a fracture when applied to a specific plane of a tablet.

Tablet cup. The distance from the tablet band to the highest point, or apex, of the tablet.

Tablet design. The criteria used by tool designers to create a new tablet.

Tablet dry coating. The process of compressing a tablet around a tablet or a tablet around a tablet around another tablet, which forms three layers. It is usually used when a tablet reacts to heat or moisture during film coating. Also known as tablet-in-tablet or compression coating.

Tablet face. The tablet surface formed by the punch tip.

Tablet identification. A logo, code, or character contour applied to a tablet surface by means of debossing or embossing on tablet tooling; used to distinguish one product from another.

Tablet press. A machine that compacts a mixture of powders or granules into a single tablet by applying pressure. The process is carried out in a die between two punches.

Tablet thickness. The combined height of the two tablet cups and the tablet band.

Tableting. A punch-and-die procedure that compacts powdered or granular solids.

Tamper-evident. Used to describe packaging that has one or more safety features that indicate when it has been altered from the original condition as supplied by the manufacturer or packager.

Telescope. A defect caused by a capsule body extending up and over the cap, which can result in leakage.

Titration dosing. A method in which a dose of medication is adjusted for a patient, calculated by determining the level of the pharmacological response and changing the dose appropriately.

Tooling. A set of punches and dies to be used in a tablet press.

Transmission. The act of moisture and/or gas passing through a packaging film or foil.

Trial size. A sample of a drug given to a patient by a physician in a blister, strip pack, or small bottle. Also known as a physician sample.

Tri-layer tablet. A tablet comprising three distinct layers.

Tuck. A defect caused by a capsule cap folding under itself during closing.

21 CFR Part 11. Title 21, Code of Federal Regulations, Part 11. US regulations that establish criteria under which some electronic records and electronic signatures are considered by the FDA as equivalent to paper records and handwritten signatures.

Twinning. The bonding of tablets with large, flat surfaces during the coating process.

Two-piece capsule. A shell of fixed size made of gelatin or cellulose with or without the addition of colorants used to deliver pharmaceutical and dietary-supplement formulations. It comprises an upper part (the cap), which fits over a longer lower part (the body). The parts are separated for filling and then rejoined.

U

Unit-dose packaging. A blister pack that holds the required amount of drug products a patient takes for a single bout of treatment.

Unit of use. A drug product packaged according to the amount required for treatment.

V

Validation. A documented program that provides a high degree of assurance that a specific process, method, or system will consistently yield a result that meets predetermined specifications and quality attributes.

Viscosity. The measurement of a material's resistance to flow.

Volumetric feeding. The process of metering material according to volume, which is determined by the size and speed of the dispensing device.

W

Wallet. A package that comprises a blister pack sealed into a fold-over card.

Wash-in-place (WIP). A method of cleansing most contaminants from the interior surfaces of process equipment without disassembling it.

Wet granulation. The process of adhering particles to one another using water solutions or pastes comprising binders. The wet mass is broken up and then dried to form granules of the appropriate size. Organic solvents, such as ethanol, can be used if moisture-labile materials are used.

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