



APPENDIX B

Glossary of Pharmaceutical Terms and Dosage Forms

A

Active Ingredient: the ingredient or ingredients of a pharmaceutical product responsible for its pharmacologic activity (also medicament, drug substance, active pharmaceutical ingredient [API]).

Aerosol: a dosage form that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system. A dosage form consisting of a liquid or solid preparation packaged under pressure and intended for administration as a fine mist. The descriptive term aerosol also refers to the fine mist of small droplets or solid particles that are emitted from the product.

Aerosol Foam: a dosage form containing one or more active ingredients, surfactants, aqueous or nonaqueous liquids, and the propellant; if the propellant is in the internal (discontinuous) phase (i.e., of the oil-in-water type), a stable foam is discharged, and if the propellant is in the external (continuous) phase (i.e., of the water-in-oil type), a spray or a quick-breaking foam is discharged.

Aerosol, Metered: a pressurized dosage form consisting of metered-dose valves, which allow for the delivery of a uniform quantity of spray upon each activation.

Ampul: a final container that is all glass in which the open end, after filling with product, is sealed by heat (also ampoule, ampule, [French] carpule).

Aromatic Water: a clear, saturated, aqueous solution of volatile oils or other aromatic or volatile substances.

Aseptic: lacking disease-producing microorganisms; not the same as sterile.

Aseptic Processing: manufacturing dosage forms without terminal sterilization. The dosage form is sterile filtered, aseptically filled into the final package, and then aseptically sealed.

Aural (Auricular): for administration into, or by way of, the ear.

B

Bead: a solid dosage form in the shape of a small sphere. The dosage form generally contains multiple beads (also pellet).

Blocks: large veterinary products intended to be licked by animals and containing API(s) and nutrients such as salts, vitamins, and minerals.

Bolus: a large, long tablet intended for administration to animals.

C

Caplet: tablet dosage form in the shape of a capsule.

Capsule: a solid dosage form in which the drug is enclosed within a hard or soft soluble container or shell.

Capsule, Delayed-Release: a coated capsule or more commonly encapsulated granules that may be coated to resist releasing the drug in the stomach because the drug will irritate gastric mucosa or gastric fluid will inactivate the drug.

Capsule, Extended-Release: a capsule that is formulated in such a manner as to make the contained medication available over an extended period following ingestion.

Capsule, Film-Coated Extended-Release: a solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; additionally, the capsule is covered in a designated film coating, which releases a drug (or drugs) in such a manner to allow at least a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.

Capsule, Gelatin-Coated: a solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin; through a banding process, the capsule is coated with additional layers of gelatin so as to form a complete seal.

Capsule, Liquid-Filled: a solid dosage form in which the drug is enclosed within a soluble, gelatin shell, which is plasticized by the addition of a polyol, such as sorbitol or glycerin, and is therefore of a somewhat thicker consistency than that of a hard-shell capsule; typically, the active ingredients are dissolved or suspended in a liquid vehicle.

Capsule, Soft-Shell: a solid dosage form in which one or more active ingredients, normally in

solution or suspension or in the form of a paste, are filled into a one-piece shell.

Chewable: attribute of a solid dosage form that is intended to be chewed or crushed before swallowing.

Coated: attribute of a solid dosage form that is covered by deposition of an outer solid that is different in composition from the core material.

Collodion: a liquid preparation composed of pyroxylin dissolved in a solvent mixture of alcohol and ether and applied externally.

Colloidal Dispersion: an attribute of a preparation or formulation in which particles of colloidal dimension (i.e., typically between 1 nm and 1 μ m) are distributed uniformly throughout a liquid.

Concentrate: a liquid preparation of increased strength and reduced volume, which is usually diluted prior to administration or use.

Concentrate for Dip: a preparation containing one or more active ingredients usually in the form of a paste or solution; it is used to prepare a diluted suspension, emulsion, or solution of the active ingredient(s) for the prevention and treatment of ectoparasitic infestations of animals.

Conventional-Release: descriptive term for a dosage form in which no deliberate effort has been made to modify the release rate of the API. In the case of capsules and tablets, the inclusion or exclusion of a disintegrating agent is not interpreted as a modification.

Cream: a semisolid dosage form containing one or more drug substances dissolved or dispersed in a suitable base. An emulsion dosage form often containing more than 20% water and volatiles and/or containing <50% hydrocarbons, waxes, or polyols, as the vehicle for the API. Creams are generally intended for external application to the skin or mucous membranes.

D

Delayed-Release: a type of modified-release dosage form. A descriptive term for a dosage form deliberately modified to delay release of the API for some period of time after initial administration. For example, release of the API is prevented in the gastric environment but promoted in the intestinal environment; this term is synonymous with Enteric-Coated or Gastro-Resistant.

Dental: descriptive term for a preparation that is applied to the teeth or gums for local action.

Dermal: a topical route of administration where the article is intended to reach or be applied to the dermis.

Dosage Form: a formulation that typically contains the API(s) and excipients in quantities and physical form designed to all the accurate and efficient administration of the API to the human or animal patient.

Douche: a liquid preparation intended for the irritative cleansing of the vagina; prepared from powders, liquid solutions, or liquid concentrates.

Dressing: the application of various materials for protecting a wound.

Drops, Oral: a solution, emulsion, or suspension that is administered in small volumes, such as drops, by means of a suitable device.

Drug Delivery System: modern technology, distributed with or as a part of a drug product that allows for the uniform release or targeting of drugs to the body.

Dry Powder Inhaler: a device used to administer an inhalation powder in a finely divided state suitable for oral inhalation by the patient.

E

Effervescent: a dosage form containing ingredients that rapidly release carbon dioxide when in contact with water.

Elixir: a clear, pleasantly flavored, sweetened hydroalcoholic liquid containing dissolved active ingredients intended for oral use.

Emollient: attribute of a cream or ointment indicating an increase in the moisture content of the skin following application of bland, fatty, or oleaginous substances.

Emulsion: a two-phase system in which one liquid is dispersed throughout another liquid in the form of small droplets. A dosage form consisting of a two-phase system composed of at least two immiscible liquids, one of which is dispersed as droplets (internal or dispersed phase) within the other liquid (external or continuous phase), generally stabilized with one or more emulsifying agents.

Enema: a rectal preparation for therapeutic, diagnostic, or nutritive purposes.

Enteric-Coated: descriptive term for a solid dosage form in which a polymer coating has been applied to prevent the release of the API in the gastric environment.

Excipient: an ingredient of a dosage form other than an API.

Extended-Release: descriptive term for a dosage form that is deliberately modified to protract the release of the API compared to that observed for an immediate-release dosage form. The term is synonymous with prolonged or sustained release. Many extended-release dosage forms

have a pattern of release that begins with a “burst effect” that mimics an immediate release followed by a slower release of the remaining API in the dosage form.

Extract: a concentrated preparation of vegetable or animal drug obtained by removal of the active constituents with suitable menstrua, by evaporation of all or nearly all of the solvent, and by adjustment of the residual mass or powder to the prescribed standards.

F

Film: a thin layer or coating. A term used to describe a thin, flexible sheet of material, usually composed of a polymer. Films are used in various routes of administration including as a means of oral administration of material in a rapidly dissolving form. The term may also be used as an attribute when applied to solid oral dosage forms for taste masking, product identification, and aesthetic purposes.

Fluidextract: a liquid preparation of a vegetable drug containing alcohol as a solvent, preservative, or both and so made that unless otherwise specified in an individual monograph, each milliliter contains the therapeutic constituents of 1 g of the standard drug.

Foam: an emulsion packaged in a pressurized aerosol container that has a fluffy, semisolid consistency when dispensed. An emulsion dosage form containing dispersed gas bubbles.

For Solution: a product, usually a solid, intended for solution prior to administration.

For Suspension: a product, usually a solid, intended for suspension prior to administration.

G

Gas: one of the states of matter having no definite shape or volume and occupying the entire container when confined.

Gastro-Resistant: descriptive term for a solid dosage form in which a polymer coating has been applied to prevent the release in the gastric environment.

Gel: a semisolid system consisting of either a suspension of small inorganic particles or large organic molecules interpenetrated by a liquid. It may contain suspended particles. It may contain a gelling agent to promote stiffness.

Gel, Dentifrice: a combination of a dentifrice (formulation intended to clean and/or polish the teeth and which may contain certain additional agents) and a gel. It is used with a toothbrush for the purpose of cleaning and polishing the teeth.

Gel, Metered: a gel preparation, with metered-dose valves, which allow for the delivery of a uniform quantity of gel upon each activation.

Globule: also called pellets or pilules, are made of pure sucrose, lactose, or other polysaccharides. They are formed into small globular masses of various sizes and are medicated by placing them in a vial and adding the liquid drug attenuation in the proportion not less than 1% (w/v). After shaking, the medicated globules are dried at temperatures not to exceed 40°C.

Granules: a preparation of dry aggregates of powder particles that may contain one or more active ingredients with or without other ingredients. They may be swallowed as such, dispersed in food, or dissolved in water. Granules are frequently compacted into tablets or filled into capsules, with or without additional ingredients.

Gum: a mucilaginous excretion from various plants. A dosage form in which the base consists of a pliable material that, when chewed, releases the API into the oral cavity.

Gum, Chewing: a sweetened and flavored insoluble plastic material that, when chewed, releases a drug substance into the oral cavity.

Gum, Resin: natural mixture of gum and resin, usually obtained as exudations from plants.

H

Hard-Shell Capsule: a type of capsule in which one or more APIs, with or without other ingredients, are filled into a two-piece shell.

I

Immediate-Release: descriptive term for a dosage form in which no deliberate effort has been made to modify the API release rate. In the case of capsules and tablets, the inclusion or exclusion of a disintegrating agent is not interpreted as a modification.

Implant: see Pellet. A small sterile solid mass consisting of a highly purified drug with or without excipients made by compression or molding and put in place by injection or incision.

Infusion, Intramammary: a suspension of a drug in a suitable oil vehicle; intended for veterinary use only.

Inhalant: a special class of inhalations consisting of a drug or combination of drugs that by virtue of their high vapor pressure can be carried by an air current into the nasal passage where they exert their effect; the container from which the inhalant generally is administered is known as an inhaler.

Inhalation: a route of administration for aerosols characterized by dispersion of the API into the airways during inspiration.

Injection, Liposomal: an injection, which either consists of or forms liposomes (a lipid bilayer vesicle usually composed of phospholipids, which is used to encapsulate an active drug substance).

Injection: a preparation intended for parenteral administration or for constituting or diluting a parenteral product prior to administration. A route of administration of a liquid or semi-solid deposited into a body cavity, fluid, or tissue by use of a needle.

Insert: a specially formulated and shaped non-encapsulated solid preparation intended to be placed into a nonrectal orifice of the body, where drug is released, generally for localized effects.

Intraocular: a route of administration to deliver a sterile preparation within the eye.

Intrauterine Device: a device inserted and left in the uterus to prevent effective conception.

Irrigation: a sterile solution intended to bathe or flush open wounds or body cavities.

J

Jelly: see Gel.

L

Liniment: an alcoholic or oleaginous solution or emulsion applied by rubbing on the skin for treating pain and stiffness of underlying musculature.

Liposomes: microvesicles composed of a bilayer and/or concentric series of multiple bilayers separated by aqueous compartments formed by amphipathic molecules such as phospholipids, which enclose a central aqueous compartment.

Lipstick: a waxy solid, usually colored cosmetic, in stick form for the lips.

Liquid: a dosage form consisting of a pure chemical in its liquid state. This dosage form term should not be applied to solutions.

Lotion: a fluid emulsion applied to the surface of the skin. See Solution or Suspension. The term has also been applied to suspensions and solutions.

Lozenge: a solid preparation that is intended to dissolve or disintegrate slowly in the mouth.

Lyophilization: removal of water or other solvent from a frozen solution by sublimation caused by a combination of temperature and pressure differentials (also called freeze drying).

M

Modified-Release: a release pattern of the active ingredient from the dosage form that has been deliberately changed from that of the conventional form. It includes accelerated release, delayed release, extended release, pulsatile release, and targeted release.

Molded Tablet: a tablet that has been formed by dampening the ingredients and pressing them into a mold, then removing and drying the resulting solid mass.

Mouthwash: an aqueous solution used to rinse the oral cavity.

N

Nasal: route of administration (mucosal) characterized by deposition in the nasal cavity for local or systemic effect.

O

Ocular: route of administration indicating deposition of the API within the eye.

Oil: an unctuous, combustible substance that is liquid, or easily liquefiable, on warming and is soluble in ether but insoluble in water. Such substances, depending on their origin, are classified as animal, mineral, or vegetable oils.

Ointment: a semisolid preparation intended for external application to the skin or mucous membrane. A semisolid dosage form, usually containing <20% water and volatiles and more than 50% hydrocarbons, waxes, or polyols as the vehicle. This dosage form generally is for external application to the skin or mucous membranes.

Ophthalmic: a route of administration characterized by application of a sterile preparation to the external parts of the eye.

Ophthalmic Ointment: a sterile ointment intended for application to the eye.

Ophthalmic Preparation: drug in a dosage form intended to be applied to the eye.

Ophthalmic Solution: a sterile solution, essentially free from foreign particles, suitably prepared and packaged for application to the eye.

Ophthalmic Strip: a sterile single-use container or sterile impregnated paper strip containing the drug to be applied to the eye.

Ophthalmic Suspension: a sterile liquid preparation containing solid particles dispersed in a liquid vehicle intended for application to the eye.

Orally Disintegrating: a descriptive term for a solid oral dosage form that disintegrates rapidly in the mouth prior to swallowing. The

API is generally intended for gastrointestinal delivery and/or absorption.

Oropharyngeal: a route of administration characterized by deposition of a preparation into the oral cavity and/or pharyngeal region to exert a local or systemic effect.

Otic: a route of administration characterized by deposition of a preparation into, or by way of, the ear. Also referred to as aural.

Otic Solution: a solution intended for instillation in the outer ear.

Otic Suspension: a liquid preparation containing micronized particles intended for instillation in the outer ear.

P

Paste: a semisolid dosage form that contains one or more drug substances intended for topical application. It generally contains a high concentration of solids (20% to 50%) and has a stiff consistency. It is intended for application to the skin, oral cavity, or mucous membranes.

Pastille: an aromatic preparation, often with a pleasing flavor, usually intended to dissolve in the mouth.

Patch: a drug delivery system that often contains an adhesive backing usually applied to an external site on the body. Its ingredients either passively diffuse from or are actively transported from some portion of the patch.

Pellet: see Bead. A small solid dosage form of uniform, often spherical, shape. Spherical pellets are sometimes referred to as beads. Pellets intended as implants must be sterile. (Also a solid granule or regular shape prepared by compaction, molding, or granulation.)

Periodontal: descriptive term for a preparation that is applied around a tooth for localized action.

Pill: a solid spherical dosage form usually prepared by a wet massing technique.

Plaster: a solid or semisolid mass supplied on a backing material and intended to provide prolonged contact with the skin.

Pledget: a small compress or tuft, usually of cotton or cotton wool, used to apply disinfectant or medicament to the skin.

Poultice: a soft, moist mass of meal, herbs, seed, etc., usually applied hot on a cloth that consists of gruel-like consistency.

Powder: an intimate mixture of dry, finely divided drug and/or chemicals that may be intended for internal (oral) or external (topical) use.

Powder, Inhalation: a powder containing an API for oral inhalation. The powder is used with a device that aerosolizes and delivers an accurately metered amount.

Premix: a mixture of one or more drug substances with a suitable vehicle.

Prolonged-Release: see Extended-Release.

Pulsatile Release: a release pattern of the active ingredient from the dosage form modified to release aliquots of the total dose at two or more time intervals.

R

Radiopharmaceuticals: “radioactive pharmaceuticals,” or substances labeled with radioisotope and used for diagnostic imaging or therapy. Each name specifies the substance, the isotope, and the dosage form.

Rectal: a route of administration (mucosal) characterized by deposition into the rectum to provide local or systemic effect.

Rinse: a solution used to cleanse by flushing.

S

Salve: a thick ointment or cerate (a fat- or wax-based preparation with a consistency between an ointment and a plaster).

Semisolid: attribute of a material characterized by a reduced ability to flow or conform to its container at room temperature. A semisolid does not flow at low shear stress and generally exhibits plastic flow behavior.

Shampoo: a solution, emulsion, or suspension used to clean the hair and scalp.

Soap: the alkali salt(s) of one or more fatty acids.

Soft Gel Capsule: a specific capsule type characterized by increased levels of plasticizers producing a more pliable and thicker-walled material than hard gelatin capsules. Soft gel capsules are further distinguished because they are single-piece sealed dosages. Frequently used for delivering liquid compositions.

Solution: a liquid preparation that contains one or more dissolved (molecularly dispersed) chemical substances in a suitable solvent or mixture of miscible solvents; it may be oral, topical, otic, or ophthalmic. A clear, homogeneous liquid dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.

Solution, Concentrate: a liquid preparation (i.e., a substance that flows readily in its natural state) that contains a drug dissolved in a suitable solvent or mixture of mutually miscible solvents; the drug has been strengthened by the evaporation of its nonactive parts.

Spirit: an alcoholic or hydroalcoholic solution of volatile substances prepared usually by simple solution or by admixture of the ingredients.

Sponge: a porous, interlacing, absorbent material that contains a drug. It is typically used for applying or introducing medication or for cleansing. A sponge usually retains its shape.

Spray: a liquid minutely divided as by a jet of air or steam; used to facilitate application to the intended area

Stent, Drug-Eluting: a specialized form of implant used for extended local delivery of the API to the immediate location of stent placement.

Sterile: completely lacking living (viable) microbial life.

Sterility: an acceptably high level of probability that a product processed in an aseptic system does not contain viable microorganisms.

Stick: a slender, cylindrical dosage form of rigid consistency.

Strip: see Tape, Medicated.

Sublingual: a route of administration (mucosal) characterized by placement underneath the tongue and for release of the API for absorption in that region.

Suppository: a solid dosage form in which one or more APIs are dispersed in a suitable base and molded or otherwise formed into a suitable shape for insertion into the rectum to provide local or systemic effect.

Suspension: a liquid preparation that consists of solid particles dispersed throughout a liquid phase in which the particles are not soluble; it may be oral, topical, otic, or ophthalmic.

Swab: a small piece of relatively flat absorbent material that contains a drug. A swab may also be attached to one end of a small stick. A swab is typically used for applying medication or for cleansing.

Syrup: a solution containing a high concentration of sucrose or other sugars. See Solution.

System, Intrauterine: a system that is intended for release of drug over a long period, such as a year.

System: a dosage form developed to allow for uniform release or targeting of drugs to the body.

System, Ocular: a dosage form intended for placement in the lower conjunctival fornix, from which the drug diffuses through a membrane at a constant rate.

System, Transdermal: a self-contained, discrete dosage form that is designed to deliver drug(s) through the intact skin to the systemic circulation.

T

Tablet: a solid dosage form containing medicinal substance(s) with or without diluents.

Tablet, Chewable: a tablet formulated so that it may be chewed, producing a pleasant-tasting residue that is easily swallowed and does not leave a bitter or unpleasant aftertaste.

Tablet, Delayed-Release: a tablet with a coating that is intended to postpone the release of the medication until the tablet has passed through the stomach.

Tablet, Effervescent: a solid dosage form containing mixtures of acids and sodium bicarbonate, which release carbon dioxide when dissolved in water; it is intended to be dissolved or dispersed in water before administration.

Tablet, Extended-Release: a tablet that is formulated so as to make the contained medication available over an extended period following ingestion.

Tablet, Orally Disintegrating: a solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.

Tape, Medicated: a dosage form or device composed of a woven fabric or synthetic material onto which an API is placed, usually with an adhesive on one or both sides to facilitate topical application.

Targeted Release: release of the active ingredient from a dosage form modified to preferentially deliver most of the drug to a specific region, organ, or tissue.

Terminal Sterilization: a process used to produce sterility in the final product contained in its final packaging system.

Tincture: an alcoholic or hydroalcoholic solution prepared from vegetable materials or from chemical substances.

Topical: a route of administration characterized by application to the outer surface of the body.

Transdermal Delivery System, Electroporation: a transdermal delivery system enhanced by the application of short, high-voltage electric pulses to create aqueous pores in the lipid bilayer of the skin and thereby facilitate drug diffusion.

Transdermal Delivery System, High-Velocity Powder Particles: a transdermal drug delivery system using supersonic shock waves of helium gas to enhance drug diffusion through the skin.

Transdermal Delivery System, Iontophoresis: a transdermal drug delivery system enhanced by the use of applied electric current to facilitate drug diffusion through the skin.

Transdermal Delivery System, Phonophoresis: a transdermal drug delivery system enhanced by the application of low-frequency ultrasound to

facilitate drug diffusion through the skin (also ultrasound, sonophoresis, ultrasonophoresis, ultraphonophoresis).

Transdermal Matrix Patch: a transdermal matrix system using a polymeric matrix containing drug intended for systemic delivery through the skin; generally, the skin is the rate-controlling membrane for drug diffusion.

Transdermal Membrane Patch: a transdermal system containing a drug reservoir entrapped between backing and adhesive layers and a drug diffusion-controlling membrane; the reservoir is usually a semisolid dispersion or solution of the drug.

Troche: see Lozenge.

U

Urethral: a dosage form intended for insertion into the urethra to provide a local effect of the active ingredient.

V

Vaginal: a route of administration (mucosal) characterized by deposition into the vagina.

Vaginal Tablet or Insert: a vaginal insert prepared by compression of powdered materials into a suitable shape; it can also be prepared by encapsulation in soft gelatin.

Validation: scientific study to prove that a process is doing what it is supposed to do and is under control.

Vehicle: a term commonly encountered that refers to a component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

Veterinary: descriptive term for dosage forms intended for nonhuman use.

W

Wafer: a thin slice of a material containing a medicinal agent.

Water, Aromatic: a clear, saturated aqueous solution (unless otherwise specified) of one or more volatile oils or other aromatic or volatile substances.