



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