

CDER DATA STANDARDS MANUAL

Topical Dosage forms culled from the CDER data standards manual
(<http://www.fda.gov/cder/dsm/DRG/drg00201.htm>)

- ◆ **AEROSOL:** A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system; it is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).
- ◆ **AEROSOL, FOAM:** An emulsion containing one or more active ingredients, surfactants, aqueous or nonaqueous liquids, and the propellants; 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, POWDER:** A product that is packaged under pressure and contains therapeutically active ingredients, in the form of a powder, that are released upon activation of an appropriate valve system
- ◆ **AEROSOL SPRAY:** An aerosol product which utilizes a compressed gas as the propellant to provide the force necessary to expel the product as a wet spray; it is applicable to solutions of medicinal agents in aqueous solvents.
- ◆ **GEL:** A semisolid system consisting of either suspensions made up of small inorganic particles or large organic molecules interpenetrated by a liquid.
- ◆ **GEL, JELLY:** A class of gels--semisolid systems which consist of suspensions made up of either small inorganic particles or large organic molecules interpenetrated by a liquid--in which the structural coherent matrix contains a high portion of liquid, usually water.
- ◆ **LINIMENT:** A solution or mixture of various substances in oil, alcoholic solutions of soap, or emulsions intended for external application.
- ◆ **LIQUID:** A state of substance that is an intermediate one entered into as matter goes from solid to gas; liquids are also intermediate in that they have neither the orderliness of a crystal nor the randomness of a gas. (Note: This term should not be used to describe solutions, only pure chemicals in their liquid state.)
- ◆ **LOTION:** "The term lotion" has been used to categorize many topical suspensions, solutions and emulsions intended for application to the skin.
- ◆ **OIL:** An unctuous, combustible substance which 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 membranes.
- ◆ **PATCH:** A drug delivery system that contains an adhesived backing and that permits its ingredients to diffuse from some portion of it (e.g., the backing itself, a reservoir, the adhesive, or some other component) into the body from the external site where it is applied.
- ◆ **PATCH, EXTENDED RELEASE:** A drug delivery system in the form of a patch that releases the drug in such a manner that a reduction in dosing frequency compared to that drug presented as a conventional dosage form (e.g., a solution or a prompt drug-releasing, conventional solid dosage form).

- ◆ **PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED:** A drug delivery system in the form of a patch which is controlled by an electric current that releases the drug in such a manner that a reduction in dosing frequency compared to that drug presented as a conventional dosage form (e.g., a solution or a prompt drug-releasing, conventional solid dosage form).
- ◆ **POURICE:** A soft, moist mass of meal, herbs, seed, etc., usually applied hot in cloth that consists of gruel-like consistency.
- ◆ **POWDER:** An intimate mixture of dry, finely divided drugs and/or chemicals that may be intended for internal or external use.
- ◆ **SALVE:** A thick ointment or cerate (a fat or wax based preparation with a consistency between an ointment and a plaster).
- ◆ **SHAMPOO:** A liquid soap or detergent used to clean the hair and scalp and is often used as a vehicle for dermatologic agents.
- ◆ **SHAMPOO SUSPENSION:** A liquid soap or detergent containing one or more solid, insoluble substances dispersed in a liquid vehicle that is used to clean the hair and scalp and is often used as a vehicle for dermatologic agents.
- ◆ **SOAP:** Any compound of one or more fatty acids, or their equivalents, with an alkali; soap is detergent and is much employed in liniments, enemas, and in making pills. It is also a mild aperient, antacid and antiseptic.
- ◆ **SOLUTION:** A liquid preparation that contains one or more chemical substances dissolved, i.e., molecularly dispersed, in a suitable 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.
- ◆ **SPRAY, METERED:** A non-pressurized dosage form consisting of valves which allow the dispensing of a specified quantity of spray upon each activation.
- ◆ **SPRAY, SUSPENSION:** A liquid preparation containing solid particles dispersed in a liquid vehicle and in the form of coarse droplets or as finely divided solids to be applied locally, most usually to the nasal-pharyngeal tract, or topically to the skin.
- ◆ **SUSPENSION:** A liquid preparation which consists of solid particles dispersed throughout a liquid phase in which the particles are not soluble.
- ◆ **SUSPENSION, EXTENDED RELEASE:** A liquid preparation consisting of solid particles dispersed throughout a liquid phase in which the particles are not soluble; the suspension has been formulated in a manner to allow at least a reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution or a prompt drug-releasing, conventional solid dosage form).
- ◆ **TINCTURE:** An alcoholic or hydroalcoholic solution prepared from vegetable materials or from chemical substances