CDER Data Standards Manual Definitions for Topical Dosage Forms

Dosage Form Term	Old Definition	New Definition
Cream	A semisolid dosage form containing one or more drug substances dissolved or dispersed in a suitable base; more recently, the term has been restricted to products consisting of oil-in-water emulsions or aqueous microcrystalline dispersions of long chain fatty acids or alcohols that are water washable and more cosmetically and aesthetically acceptable.	An emulsion, semisolid[3] dosage form, usually containing >20% water and volatiles[5] and/or <50% hydrocarbons, waxes, or polyols as the vehicle. This dosage form is generally for external application to the skin or mucous membranes.
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 comprised of at least two immiscible liquids[1], 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. (Note: Emulsion is used as a dosage form term unless a more specific term is applicable, e.g. cream, lotion, ointment.)
Gel	A semisolid system consisting of either suspensions made up of small inorganic particles or large organic molecules interpenetrated by a liquid.	A semisolid[3] dosage form that contains a gelling agent to provide stiffness to a solution or a colloidal dispersion.[4] A gel may contain suspended particles.
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.)	A dosage form consisting of a pure chemical in its liquid[1] state. This dosage form term should not be applied to solutions.
Lotion	The term lotion has been used to categorize many topical suspensions, solutions, and emulsions intended for application to the skin.	An emulsion liquid[1] dosage form. This dosage form is generally for external application to the skin.[2]
Ointment	A semisolid preparation intended for external application to the skin or mucous membranes.	A semisolid[3] dosage form, usually containing <20% water and volatiles[5] and >50% hydrocarbons, waxes, or polyols as the vehicle. This dosage form is generally for external application to the skin or mucous membranes.
Paste	A semisolid dosage form that contains one or more drug substances intended for topical application.	A semisolid[3] dosage form, containing a large proportion (20 – 50%) of solids finely dispersed in a fatty vehicle. This dosage form is generally for external application to the skin or mucous membranes.
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.	A clear, homogeneous liquid[1] dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.

Suspension	A liquid preparation which consists of solid particles throughout a liquid phase in which the particles are not soluble.	A liquid[1] dosage form that contains solid particles dispersed in a liquid vehicle.

[1] A liquid is pourable; it flows and conforms to its container at room temperature. It displays Newtonian or pseudoplastic flow behavior.

[2] Previously the definition of a lotion was "The term lotion has been used to categorize many topical suspensions, solutions, and emulsions intended for application to the skin." The current definition of a lotion is restricted to an emulsion.

[3] A semisolid is not pourable; it does not flow or conform to its container at room temperature. It does not flow at low shear stress and generally exhibits plastic flow behavior.

[4] A colloidal dispersion is a system in which particles of colloidal dimension (i.e. typically between 1 nm and 1 μm) are distributed uniformly throughout a liquid.

[5] Percent water and volatiles are measured by a loss on drying test in which the sample is heated at 105°C until constant weight is achieved.