

## CDER Data Standards Manual Definitions for Topical Dosage Forms

| Dosage Form Term | Old Definition   | New Definition   |
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| 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 <sup>3</sup> dosage form, usually containing >20% water and volatiles <sup>5</sup> 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 <sup>1</sup> , 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 <sup>3</sup> dosage form that contains a gelling agent to provide stiffness to a solution or a colloidal dispersion. <sup>4</sup> 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 <sup>1</sup> 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 <sup>1</sup> dosage form. This dosage form is generally for external application to the skin. <sup>2</sup>  |
| Ointment         | A semisolid preparation intended for external application to the skin or mucous membranes.   | A semisolid <sup>3</sup> dosage form, usually containing <20% water and volatiles <sup>5</sup> 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 <sup>3</sup> 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 <sup>1</sup> dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.  |

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| Suspension | A liquid preparation which consists of solid particles throughout a liquid phase in which the particles are not soluble. | A liquid <sup>1</sup> dosage form that contains solid particles dispersed in a liquid vehicle. |
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<sup>1</sup> A liquid is pourable; it flows and conforms to its container at room temperature. It displays Newtonian or pseudoplastic flow behavior.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> A colloidal dispersion is a system in which particles of colloidal dimension (i.e. typically between 1 nm and 1  $\mu$ m) are distributed uniformly throughout a liquid.

<sup>5</sup> 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.