

Questions for 3/12/03 ACPS on Topical Dosage Form Nomenclature
2/12/03

1. The appearance and feel of a topical dosage form is part of the proposed definitions. In conversations with practitioners and evaluation of the literature, words such as greasy, non-greasy and cooling are often used when describing these dosage forms. Is there any value in including these attributes in the definitions?
2. Laboratory work found viscosity to be the most discriminating property that separated lotions from creams. In addition most literature sources describe lotions as liquids and creams as semi-solids. In the proposed definitions, lotion is distinguished from cream based on “pourability” which we found in the lab to be a viscosity less than 30,000 cp using the Brookfield viscometer at 25°C and 5 rpm. Is this reasonable?
3. Laboratory work found LOD to be a discriminating property that separated ointments from creams. In addition, a review of the current submissions to ONDC and OGD found that ointments had large percentages of hydrocarbons or PEGs in their bases. In the proposed definitions, ointment is distinguished from cream based on the proportions of volatiles (< 20% LOD) and composition (hydrocarbons or PEGs > 50%). Is this reasonable?
4. The distinction between hydrophilic and lipophilic creams is made based on the composition of the continuous phase. Is there any value in including these two types of creams in the definitions?
5. (a) Gel is distinguished from cream based on the presence of sufficient quantities of a gelling agent to form a three-dimensional, cross-linked matrix. Is this reasonable? Should “sufficient quantities” be defined? Which literature sources should be used as references?
(b) Some currently marketed “gels” contain an emulsifier that gives the dosage form an opaque appearance. Should the presence of an emulsifier in a formulation preclude a dosage form from being classified as a gel? Should it then be considered a cream instead of gel?
(c) What is the most appropriate analytical technique that can be used to identify the three dimensional structure of a gel?
6. Is the overall approach taken in the proposed definitions appropriate?