Topical Dosage Form Classification

A team was assembled from the Office of Testing and Research (OTR), Office of Generic Drugs (OGD) and Office of New Drug Chemistry (ONDC) to establish a scientific basis for a systematic and coherent classification of dosage forms for topical drugs.

Background:
The existing classification of dosage forms for topical drugs needs to be re-examined to ensure that definitions for different dosage forms are consistent and that dosage forms can be distinguished from each other on the basis of clearly defined criteria. Dosage forms for new drugs need to fall into mutually exclusive classifications. Current definitions of ointment, paste, lotion, cream, and gel vary widely depending on literature source, market history, traditional use (every-day practice) or application type. For the purposes of this investigation, topical drugs refer to those dermatological drugs administered to the skin, defined as a spot on the outer surface of the body. Drugs meant for application to the oral, nasal, aural, vaginal or rectal areas were not considered. Development of definitions was limited to ointment, paste, lotion, cream and gel. A team consisting of scientists from ONDC, OGD and OTR used the following steps to develop a clear, concise, and science-based classification (nomenclature) system for topical dosage forms.

Action Plan:

1. Identify current practices in labeling or specifications for topical drugs at FDA and USP.
   - Current information on the dosage forms of interest from the USP and the CDER Standards manual are included in the attachments.

2. Review properties and formulations of topical drug products in current NDA and ANDA submissions to OGD and ONDC. The composition, appearance and viscosity of the dosage forms of interest in current NDAs/ANDAs were reviewed. Viscosities provided in these NDAs/ANDAs could not be compared because of varying conditions and techniques used by the applicants. Creams, ointments, gels and lotions with varying compositions and appearances were chosen for testing in the OTR laboratory.

3. Clarify with medical reviewers any efficacy significance associated with definitions of topical dosage forms (clinical impact). On the advice of medical reviewers, appearance and feel were added as part of the definition of these dosage forms.

4. Consult formulation and physical pharmacy textbooks for definitions. Some examples of information found in textbooks and the literature are included in the attachments.

5. Evaluate over the counter and current submissions for physical properties (viscosity, loss on drying, appearance, surface tension, composition) to determine methodologies which might be appropriate to facilitate classification. Data from these studies will be presented at the advisory meeting.

Attachments:

1. Topical dosage from definitions from the CDER Data Standards Manual

2. Topical dosage form definitions from USP <1151> Pharmaceutical Dosage Forms

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Attachments (cont.)

3. Decision Tree

4. Proposed Definitions for Topical Dosage Forms

5. Questions to the Advisory Committee

6. Textbook and Literature References


Formulation of Dermatological Vehicles, p. 528-531

Gel and Lotions: p. 745-748
Ointments: p.845-848
Other Medicated Applications: p.856

Chapter 5: Topical Suspensions p. 183 – 207
Chapter 10: Gels p. 399-411