General Chapter <1151> Pharmaceutical Dosage Forms

Type of Posting: General Announcement

Posting Date: 06–Oct–2009

This general information chapter on official preparations is proposed for revision in its entirety. The proposed revision incorporates concepts outlined in a Stimuli to the Revision Process article, Development of a Compendial Taxonomy and Glossary for Pharmaceutical Dosage Forms, published in PF 29(5). The Stimuli article proposed a tiered categorization for pharmaceutical dosage forms proceeding from route of administration to physical form and ultimately release pattern. This proposed general information chapter emphasizes the second tier of the compendial taxonomy, the physical dosage form, rather than the route of administration, with the intention of avoiding redundancy for dosage forms given by multiple routes.

The proposed revision is organized into four sections providing discussion of general considerations, product quality tests, dosage form monographs, and a glossary.

This general information chapter is intended to be supplemented by general test chapters providing more detailed discussion based on route of administration. Early drafts of such concepts relating to topical and transdermal dosage forms are presented in PF 35(3) [May-June 2009]. Proposed general test chapter <3> Topical and Transdermal Drug Products—Product Quality Tests, providing quality testing procedures, complements the performance testing proposed in <725> Topical and Transdermal Drug Products—Product Performance Tests. Additional revision proposals of similar standards for the oral (gastro-intestinal), mucosal, by inhalation, and by injection routes are planned.

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