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PRESENTATION ABSTRACT

Title: Future of Excipient Performance Testing in USP: Excipient Performance Chapter <1059>

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Abstract: Excipients play a critical role in the performance, stability and manufacturing of pharmaceutical dosage forms. The properties of excipients that ensure satisfactory and consistent performance depend on the dosage form, the product, the manufacturing process, and the performance requirements. While pharmacopeial monographs provide methods and specifications that assure excipient quality, purity and identity, other excipient properties that are critical to dosage form performance may not be identified or specified in compendial monographs. Nevertheless, general tests, procedures, and techniques provided in compendia may be used to evaluate some critical material attributes of excipients. While excipient function (e.g., functionality) is a broad, qualitative, and descriptive term for the purpose or role an excipient serves in a formulation, the quantitative performance requirements (e.g., critical material attributes) of excipients that must be evaluated and controlled to ensure consistent performance throughout the product life-cycle are of greater importance. Not all critical material attributes of an excipient may be identified or evaluated by specific tests and specifications in excipient monographs. It is therefore important that excipient users identify and control critical material attributes that go beyond monograph specifications. The draft General Information Chapter, Excipient Performance <1059> prepared by the USP Excipient General Chapters Expert Committee and an Expert Advisory Panel contains sections organized by common dosage form usage that describe a number of functional categories identified in USP/NF. Each section provides a summary of the functional mechanism as well as information about the physical and chemical properties of excipients that may be useful in ensuring consistent and desirable excipient performance.

REFERENCE: **USP GENERAL INFORMATION CHAPTER, *EXCIPIENT PERFORMANCE* <1059>,** *PHARMACOPEIAL FORUM, 35(5), 2009*