

[Stimuli Article: The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities](#)

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Expert Committee: Excipient Impurities Joint Subcommittee

The USP Excipient Impurities Joint Subcommittee comprising of member of the Excipient Monographs 1 and Excipient Monographs 2 Expert Committees will publish a *Stimuli* article targeted for *Pharmacopeial Forum* (PF) 44(3) [May–June 2018]. In this *Stimuli*, the Subcommittee will discuss the challenges in setting compendial specifications for excipient composition and impurities and the need to provide clear guidance on how to specify excipient composition, including control of impurities.

The *Stimuli* article is intended to 1) provide the views of the Subcommittee on the complexity of excipient composition; 2) introduce definitions for excipient composition, simple excipient, complex excipient, and excipient impurity; and 3) provide a proposed direction and guidance in standards setting and establishing specifications for excipient components and impurities.

The Subcommittee is considering development of a general information chapter that would provide guidance on setting specifications for excipient composition and impurities. The subcommittee is seeking input from the manufacturers and users of excipients. Input from all stakeholders is critical to the development of composition and impurity specifications.

To facilitate these goals, a survey will be launched concurrently with this *PF* publication to obtain feedback and comments from stakeholders regarding the idea of developing a general chapter on excipient composition and impurities in excipients.

When published, the links to the *Stimuli* article and survey will be available in the Excipients section of the USP website at www.usp.org/excipients.

All interested parties are encouraged to comment on the views and approaches presented by the Excipient Impurities Joint Subcommittee in this *Stimuli* article.

Comments will be accepted until July 31, 2018, the end of the comment period for *PF* 44(3).

Should you have any questions or comments, please contact Galina Holloway, Ph.D., Senior Scientific Liaison (gvh@usp.org or 301 816-8133).