USP Seeks Submission of Proposals for Monograph Modernization

Type of Posting: General Announcement

Posting Date: 28–May–2010

USP is seeking submission of proposals to support the modernization of *USP–NF* small molecule and excipient monographs that utilize outdated technology (e.g., use of packed gas chromatography columns), have safety/environmental concerns (e.g., chlorinated solvents, etc) or are missing procedures for key aspects such as impurities. For excipients, a major modernization goal is to replace relatively non-specific identification procedures with specific procedures (e.g., IR spectroscopy). USP has identified and prioritized the top 200 small molecules monographs and 96 excipient monographs in need of modernization. This list and other information regarding the submission of proposals are available on the USP website. USP is planning monthly updates to the spreadsheet on the last Friday of each month.

In order for USP to maintain consistency with FDA-approved control strategies, USP prefers to receive submissions from manufacturers of FDA-approved products (including drug substances and excipients that are known to be used in FDA-approved products) or manufacturers intending to seek FDA approval. The latter category of submissions will be initially considered for publication as a Pending standard (see USP Pending Monograph Guidelines). Submissions, especially new impurity procedures, from other sources (e.g., contract laboratories, academic institutions, analytical instrumentation/equipment manufacturers) can be accepted on a case-by-case basis and should follow ICH Q3 guidelines.

Should you have questions, please contact Jon Clark, M.S., Vice President, Chemical Medicines (jec@usp.org or 240-221-2099) or Catherine Sheehan, M.S., Director, Excipients (cxs@usp.org or 301-816-8262).

- Download the USP–NF Monograph Modernization list