

USP Dietary Supplements Stakeholder Forum
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Revision of USP General Chapter <467> Residual Solvents

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Revision Timeline

- ▶ Residual Solvents Expert Panel convened on December 2012 with the charge to: “Rewrite Chapter <467> Residual Solvents”
- ▶ A survey was conducted in the Pharmaceutical Industry during 2013 on the use of the chapter and ways to improve and enhance it.
- ▶ Proposed Revision was published in Pharmacopeial Forum 41 (5).
- ▶ A total of 136 comments/suggestions were received from 22 organizations.
- ▶ The Expert Panel held a meeting on March 17-18 2016 to address the comments

<467> Revision Path Forward

- ▶ The Residual Solvent Expert Panel decided to revise the proposal of PF 41(5) and republish in a future PF.
- ▶ The Panel decided also to move the Validation and Verification sections of the PF 41(5) proposal to a General Information Chapter (above 1000).
- ▶ The following represent some of the expected changes from the PF 41(5) document
 - Adding flexibility for the Validation of Alternative Procedures section
 - Simplifying and clarifying the control strategy options section
 - Clarifying the options for Class 3 solvents analysis



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Discussions



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Thank You