

Does International Harmonization of the USP Microbial Limits Tests Require Re-Validation of Finished Product Tests?

By **Scott Sutton, Ph.D.** May 21, 2013 2:58 pm EDT

The final versions change the requirement for validation to “verification of suitability of the method” The Microbial Limits Tests are a collection of tests and specifications. United States Pharmacopeia (USP)-National Formulary (NF) chapter <61> looks to bioburden testing (total aerobic microbial count [TAMC] and total yeast and mold count [TYMC]) while USP <62> describes tests for the “absence of” seven different specified organisms. USP <111> is an informational chapter for setting microbial quality standards for non-NF materials. USP <61> describes...

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