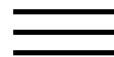


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Validation of high-performance liquid chromatography methods for pharmaceutical analysis: Understanding the differences and similarities between validation requirements of the US Food and Drug Administration, the US Pharmacopeia and the International Conference on Harmonization

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Abstract

One of the most critical factors in developing pharmaceutical drug substances and drug products today is ensuring that the HPLC analytical test methods that are used to analyze the products generate meaningful data. The US Food and Drug Administration (FDA) and United States Pharmacopeia (USP) have each recognized the importance of this to the drug development process and have separately increased validation requirements in recent years. A third source, the International Conference on

requirements in recent years. From these sources, the International Conference on Harmonization (ICH), has added requirements that, when combined with the previous two sources, have led to three different sets of validation requirements leaving the industry in a state of confusion. This paper is written to clear up the confusion over the validation requirements that are presented by each of these three sources.



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Keywords

Validation; Pharmaceutical analysis; US Food and Drug Administration; US Pharmacopeia; International Conference on Harmonization

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