

## Compliance Case Study #4— Cleaning Validation Unknown HPLC Peaks

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A compliance case study involving cleaning validation and the observation of unknown peaks in high performance liquid chromatography (HPLC) chromatograms is discussed. Unknown peaks were observed from testing of swab samples following cleaning of suspension products containing insoluble active drug, suspending agents, colors, and flavors. Equipment was visually clean. Following the original failures, a “shotgun” approach with a new cleaning procedure was attempted but was unsuccessful. Technical personnel then conducted laboratory studies using multiple cleaning agents based on the chemical and...

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