

Residue Default Limits—What, Why, and When?

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Cleaning validation acceptance limits are typically established based on a tiered approach. The first tier is the (patient) safety-based limit, and the second tier is the default limit (e.g., 10 ppm). Equipment is required to be visually clean after cleaning. After an adequate data set has been collected, the default limit may need to be adjusted based on process capabilities for future cleaning validation. Download "Residue Default Limits—What, Why, and When?"

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