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Potency Testing

ARL offers two potency test options, non-cGMP and cGMP, for determining the concentration of the active pharmaceutical ingredient (API) in compounded preparations.

	non-cGMP	cGMP
Guidelines	Specific to the analyte of interest (typically the API) based on USP guidelines for system suitability data such as retention time of the standard and sample, peak shape and absence of interfering peaks in the diluent / blank chromatogram.	Specific to the analyte of interest (typically the API) based on USP and FDA guidelines for system suitability data such as ability of the method to detect the analyte in the presence of impurities and matrix components in the specific drug product formulation.
Methods	Published or internally developed methods	Internally developed and validated or verified externally validated methods (e.g. USP)
System Suitability	ARL performs system suitability using one reference standard per API to verify the analytical method's performance.	ARL performs system suitability using two reference standards per API to verify the analytical method's performance.
Standards	Reference standards are typically secondary standards. Secondary standards are often qualified as USP grade and are obtained from reputable vendors. In some instances reference standards may be provided by the client.	USP or other primary reference standards are used. Each test also includes a secondary standard or a duplicate preparation of the primary standard as the quality control standard.
Certificate of Analysis	Certificate of Analysis states the general analytical method (e.g. HPLC) used to perform the test and includes the following statement: The method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation. *Updated November 13, 2017*	Certificate of Analysis includes a reference to the validated analytical test method number (e.g. AMI-XXXX). No statements are added as the methods are validated specifically for the formulation tested and the specifications are established by the client.

If you have questions regarding availability of cGMP test methods, stability indicating methods, or other questions, please contact ARL at 405-271-1144 or info@arlok.com.