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# Validated Analytical Potency Methods - HPLC vs. AMIF FAQ

**Q. What is the difference between HPLC and AMIF test methods?**
Both HPLC and AMIF test methods use the HPLC instrument to test the potency of active pharmaceutical ingredients (APIs) in a compounded preparation.

The difference between HPLC and AMIF test methods is the HPLC method is a non-validated method and AMIF is a validated method.

**Q. What is the difference between a non-validated and validated method?**
A non-validated method is a published or internally developed method for a specific API based on USP guidelines.

A validated method is an internally developed and verified method for a specific API based on USP, FDA, and ICH guidelines.

**Q. Why does my CofA say AMIF method?**
ARL has developed validated methods using the HPLC instrument for the most commonly tested APIs. The validated methods are designated on the CoA as AMIF.

The validation protocols and criteria are based on requirements in USP <1225> as well as FDA and ICH guidelines. The validation includes specificity, system suitability, accuracy, filter qualification, precision, and linearity and is designed to fit the intended purpose for testing the potency of your API.

Potency testing using these validated methods is provided at no additional cost and allows us to remove the non-validated disclaimer from the CoA.