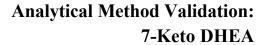


## **Analytical Method Validation:** 7-Keto DHEA

A reverse phase HPLC method with UV detection was developed and validated for 7-Keto DHEA. The validation was designed to fit the method's intended purpose and based on requirements set forth in the USP <1225> Validation of Compendial Procedures and USP <621> Chromatography, as well as FDA and ICH guidelines.

## Summary of Validation Data – 7-Keto DHEA 40ppm

Test performed	Criteria	Results	Pass/Fail
Specificity	No interference between the drug peak and any other peaks	No Interference	Pass
System Suitability	The peak areas for the 5 reference standard injections have a Relative Standard Deviation (RSD) of $\leq$ 2.0% and No interference between the drug peak and any other peaks	% RSD = 0.3 and No Interference Observed	Pass
Accuracy	The test results for the drug tested at 3 concentrations must be within 5.0% of the expected result	Low = 100.2% Med = 101.1% High = 102.0%	Pass
Filter Qualification	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Difference = 0.9%	Pass
Precision	The RSD for triplicate test results at 3 concentrations is $\leq 2.0\%$	% RSD = 0.9	Pass
Linearity	The coefficient of determination $(R^2)$ of all test results is $\geq 0.99$ and The Y-Intercept is $\leq 5.0\%$ of the response at the nominal concentration	$R^2 = 0.9998$ and Y-Intercept = 0.8%	Pass





## Summary of Validation Data – 7-Keto DHEA 400ppm

Test performed	Criteria	Results	Pass/Fail
Specificity	No interference between the drug peak and any other peaks	No Interference	Pass
System Suitability	The peak areas for the 5 reference standard injections have a Relative Standard Deviation (RSD) of $\leq$ 2.0% and No interference between the drug peak and any other peaks	% RSD = 0.1 and No Interference Observed	Pass
Accuracy	The test results for the drug tested at 3 concentrations must be within 5.0% of the expected result	Low = 101.0% Med = 101.4% High = 101.1%	Pass
Filter Qualification	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Difference = 0.4%	Pass
Precision	The RSD for triplicate test results at 3 concentrations is $\leq 2.0\%$	% RSD = 0.2	Pass
Linearity	The coefficient of determination $(R^2)$ of all test results is $\geq 0.99$ and The Y-Intercept is $\leq 5.0\%$ of the response at the nominal concentration	$R^2 = 0.9999$ and Y-Intercept = 0.3%	Pass

Validation performed according to ARL QUP-027-V1.

Experimental data recorded under ARL 529422-01.

Future analysis of 7-Keto DHEA will follow the guidelines set forth in AMIF-1884.