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 ≤ 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 ≤ 2.0%	% RSD = 0.9	**Pass**
Linearity	The coefficient of determination (R^2) of all test results is ≥ 0.99 and The Y-Intercept is ≤ 5.0% of the response at the nominal concentration	R^2 = 0.9998 and Y-Intercept = 0.8%	**Pass**

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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 ≤ 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 ≤ 2.0%	% RSD = 0.2	**Pass**
Linearity	The coefficient of determination (R^2) of all test results is ≥ 0.99 and The Y-Intercept is ≤ 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.