

Summary of Validation Data – Levothyroxine Sodium Low

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 = 0.5 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 = 101.3% Med = 100.6% High = 101.2%	Pass
Filter Qualification	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Difference = 0.7%	Pass
Precision	The RSD for triplicate test results at 3 concentrations is $\leq 2.0\%$	% RSD = 0.4	Pass
Linearity	The coefficient of determination (R^2) of all test results is ≥ 0.99 and The Y-Intercept is $\leq 5.0\%$ of the response at the nominal concentration	$R^2 = 1.0000$ and Y-Intercept = 0.2%	Pass

Summary of Validation Data – Levothyroxine Sodium High

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 = 101.5% Med = 100.7% High = 101.4%	Pass
Filter Qualification	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Difference = 0.1%	Pass
Precision	The RSD for triplicate test results at 3 concentrations is $\leq 2.0\%$	% RSD = 0.4	Pass
Linearity	The coefficient of determination (R^2) of all test results is ≥ 0.99 and The Y-Intercept is $\leq 5.0\%$ of the response at the nominal concentration	$R^2 = 1.0000$ and Y-Intercept = 0.2%	Pass

Validation performed according to ARL QUP-027-V1.

Experimental data recorded under ARL 526461-01.

Future analysis of Liothyronine Sodium and Levothyroxine Sodium will follow the guidelines set forth in AMIF-1879-V1.