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 ≤ 2.0% and No interference between the drug peak and any other peaks	% RSD = 0.8 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 = 98.4% Med = 100.5% 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 = 1.7%	**Pass**
Precision	The RSD for triplicate test results at 3 concentrations is ≤ 2.0%	% RSD = 1.9	**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 = 1.3%	**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 ≤ 2.0% and No interference between the drug peak and any other peaks	% RSD = 0.2 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 = 100.1% 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 = 0.2%	**Pass**
Precision	The RSD for triplicate test results at 3 concentrations is ≤ 2.0%	% RSD = 0.6	**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 = 0.5%	**Pass**

Validation performed according to ARL QUP-027-V1.
Experimental data recorded under ARL 526460-01.
Future analysis of Liothyronine Sodium and Levothyroxine Sodium will follow the guidelines set forth in AMIF-1878-V1.