Analytical Method Validation: Alprostadil in a mixture

A reverse phase HPLC method with UV detection was developed and validated for Alprostadil. 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 – 50ppm

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 = 99.1% Med = 99.5% High = 100.6%	**Pass**
Filter Qualification	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Filtration is not required	**N/A**
Precision	The RSD for triplicate test results at 3 concentrations is ≤ 2.0%	% RSD = 0.8	**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 = 1.0000 and Y-Intercept = 1.2%	**Pass**

Summary of Validation Data – 500ppm

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 = 0.2 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 = 101.1% Med = 100.3% High = 100.5%	**Pass**
Filter Qualification	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Filtration is not required	**N/A**
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 = 0.9994 and Y-Intercept = 0.6%	**Pass**

Validation performed according to ARL QUP-027-V1.
Experimental data recorded under ARL 523209-01.
Future analysis of Alprostadil will follow the guidelines set forth in AMIF-1867.