Analytical Method Validation: Neostigmine Methylsulfate

A reverse phase HPLC method with UV detection was developed and validated for Neostigmine Methylsulfate. 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

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 = 0.4 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 = 99.7% Med = 99.3% High = 98.9%	**Pass**
Filter Qualification	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Difference = 0.05%	**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 = 0.6%	**Pass**

Validation performed according to ARL QUP-027-V1.
Experimental data recorded under ARL 536948-01.
Future analysis of Neostigmine Methylsulfate will follow the guidelines set forth in AMIF-1903.