

## Analytical Method Validation: Papaverine HCl and Phentolamine Mesylate

A reverse phase HPLC method with UV detection was developed and validated for Papaverine HCl and Phentolamine Mesylate. 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 – Papaverine HCl

Test performed	Criteria	Results	Pass/Fail
<b>Specificity</b>	No interference between the drug peak and any other peaks	No Interference	<b>Pass</b>
<b>System Suitability</b>	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	<b>Pass</b>
<b>Accuracy</b>	The test results for the drug tested at 3 concentrations must be within 5.0% of the expected result	Low = 101.7% Med = 100.8% High = 100.4%	<b>Pass</b>
<b>Filter Qualification</b>	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Filtration is not required	<b>N/A</b>
<b>Precision</b>	The RSD for triplicate test results at 3 concentrations is $\leq 2.0\%$	% RSD = 0.7	<b>Pass</b>
<b>Linearity</b>	The coefficient of determination ( $R^2$ ) of all test results is $\geq 0.99$ and The Y-Intercept is $\leq 5.0\%$ of the response at the nominal concentration	$R^2 = 1.0000$ and Y-Intercept = 0.7%	<b>Pass</b>

## Summary of Validation Data – Phentolamine Mesylate

Test performed	Criteria	Results	Pass/Fail
<b>Specificity</b>	No interference between the drug peak and any other peaks	No Interference	<b>Pass</b>
<b>System Suitability</b>	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	<b>Pass</b>
<b>Accuracy</b>	The test results for the drug tested at 3 concentrations must be within 5.0% of the expected result	Low = 100.9% Med = 100.7% High = 100.6%	<b>Pass</b>
<b>Filter Qualification</b>	The test results of a filtered sample must be within 2.0% of the test results for an unfiltered sample	Filtration is not required	<b>N/A</b>
<b>Precision</b>	The RSD for triplicate test results at 3 concentrations is $\leq 2.0\%$	% RSD = 0.2	<b>Pass</b>
<b>Linearity</b>	The coefficient of determination ( $R^2$ ) of all test results is $\geq 0.99$ and The Y-Intercept is $\leq 5.0\%$ of the response at the nominal concentration	$R^2 = 1.0000$ and Y-Intercept = 0.1%	<b>Pass</b>

Validation performed according to ARL QUP-027-V1.

Experimental data recorded under ARL 523210-01.

Future analysis of Papaverine HCl and Phentolamine Mesylate will follow the guidelines set forth in AMIF-1868.