Chemical Solutions, Inc.
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South New Berlin, NY 13843

SPREADSHEET VALIDATION PROTOCOL

FOR HPLC PQ KIT EXCEL TEMPLATE Rev. 7.07

Protocol No P20521A

Prepared By: _____

Date: 5/21/12

Jeremy Dowling
Dowling IT

Approved By: _____

Date: 5/21/12

Richard Hartwick
Chemical Solutions, Inc.

I. Purpose:

A. This validation protocol is intended to document and validate the HPLC PQ Kit Excel Template Rev. 7.07 used for HPLC qualifications with the PQ Kit.

II. Scope:

A. This validation is intended to demonstrate that results obtained from the spreadsheet template are accurate, and that the spreadsheet is functional in terms of formatting and printing.

B. The Instructions and assumptions must be adhered to during use. While some protection is in place against incorrect usage, validation expects that these parameters are followed. Instructions and assumptions are contained in the template, and are reproduced below:

Assumptions:

Instructions in the PQ Kit manuals were followed

III. Introduction:

This spreadsheet is provided for use in calculation of results for HPLC qualifications when using the PQ Kit. This validation will demonstrate that results obtained using this spreadsheet are accurate, and that the spreadsheet functions correctly within its design parameters.

IV. Risk Assessment

A. Risk is moderate, based on the fact that this spreadsheet serves to determine the suitability of an HPLC for analysis by a variety of companies. Any calculation or reporting errors present a potential risk that an HPLC may incorrectly be identified as suitable for use, when it is in fact unsuitable.

V. DESIGN QUALIFICATION

A. Template requirements

The requirements for the spreadsheet template are shown in Table 1.

Table 1: Spreadsheet template requirements

User Requirement Specifications	*Functional Requirement Specifications*
All calculations are accurate	- Cell formulas all must be correct. User entries are minimized.
Users can not change calculations	- All cells except those which users need to enter data are locked, and the sheets are protected.
Robustness of Overall User Interface	Cells for data input are color-coded. Drop-down selections are available where appropriate. Unexpected data entry, e.g. entering text data when only numeric data is allowed, or entering negative values when only positive values are possible, result in a warning or rejection of data by the cells.
Excel Version Compatibility	Excel software has undergone numerous revisions over time. Compatibility will be checked against Excel 2002 and 2010.

VI. INSTALLATION QUALIFICATION

A. Introduction:

The HPLC PQ template has been developed over years of operation. Changes to the template have been under revision control. The current HPLC PQ template has been assigned as category 7, with a current revision number of 06.

The template is distributed either on disk, or via downloading. Proper installation of Excel is assumed. It is necessary that the Data Analysis Toolpak is also activated. Security settings of Low or Medium are required, to enable proper operation of the macros.

VII. OPERATIONAL QUALIFICATION PROTOCOL

A. The operational qualification is intended to generate documented evidence that the spreadsheet template has been developed and operates according to user requirement specifications. Test scripts are provided in Appendix A that will be used to execute the OQ procedures.

B. Resources and Assumptions

1. All Scope assumptions are met by any instructions provided. Where instructions are general, Scope instructions are to be used.

2. Any client computers used to execute test have Windows 2000 or higher installed.

C. General Instructions

Each test script contains a series of tests that will be executed by a tester. The tester should review all steps in the script prior to initiating testing. For each test the tester should:

- Record the actual results in the "Actual Result" column as either a "Y" (denoting that the Actual Result was met) or an "N" (denoting that the Actual Result was not met). If an Actual Result was not met, the user should make a note in the Tester's Comment section explaining the Actual Result and any reasons for the difference.
- Screen printouts can be attached at the discretion of the tester. If the tester does include an attachment to demonstrate Actual Results, the tester will check the box labeled "Hardcopy Attached". The presence of the hardcopy checkbox does not indicate that an attachment is required.
- If the tester requires more space, the tester may add additional pages of Tester's Comments to the script.
- Initial and date each page of the script at the start of each page. When all tests have been completed on a page, sign the bottom of the page.
- Sign, date and record the step number for every attachment page as they are completed
- If any deviations from the script are encountered, follow the Error Resolution Process (below).

D. Error Resolution Process

1. If an error or deviation is due to an entry or typographical error, the user should note the error in the Tester's comments section and describe the impact to the test. No further action is necessary.
2. If the error or deviation is more serious than an entry or transcription error, an investigation should be performed and documented.

E. Template Specifications

The user specifications are repeated below in Table 2, with specification references. Scripts are provided in Appendix A for testing against these specifications. The scripts relevant to testing the specification are shown in the Scripts column.

Table 2: Administration Kit Requirements	
User Requirement Specifications	*Scripts*
URS E1. All calculations are accurate	S1
URS E2. Users can not change calculations	S1
URS E3. Robstness of User Interface	S2
URS E4. Excel Version Compatibility	S1 – note the Excel revision used for testing

Appendix A:

OQ Scripts

SCRIPT NUMBER: S1

SCRIPT NAME: Template Validation Script

URSs Tested: E1-3

OBJECTIVE: Document the ability of the spreadsheet template to perform according to User Requirement Specifications.

ASSUMPTIONS:

- Tester has been trained in the use of the components used.
- Hardcopy of the step execution can be attached at the discretion of the tester.

NOTES:

- Where specific instructions are needed, refer to the instructions provided within the spreadsheet template.

Flow Rate Qualification				
Leave Flow Rate found empty. Enter the following volumetric data:				
Flow:	VF Size:	Minutes:	Seconds:	% Accuracy:
0.5 mL/min	5.0 mL	10 min	3 sec	Compare Excel accuracy to hand calculation
1.0 mL/min	5.0 mL	5 min	3 sec	
5.0 mL/min	25.0 mL	4 min	50 sec	

Column Oven Temperature Qualification		
Nominal:	Observed °C:	Observations:
20°C	20.5 °C	Should Meet +/- 5°C
40°C	39.8 °C	Should Meet +/- 5°C
60°C	59.7 °C	Should Meet +/- 5°C
80°C	78.5 °C	Should Meet +/- 5°C

Autosampler Precision		
Retention times:	Areas:	Observations:
1.334	982.6	Confirm calculation accuracy using a hand-calculator
1.333	983.1	
1.332	983.2	
1.331	983.4	
1.328	981.8	
1.327	979.8	
1.326	981.2	
1.325	980.1	
1.325	979.9	
1.324	981.3	

Detector Linearity		
Peak Areas:	Heights:	Observations:
4.33	1.759	Confirm calculation accuracy using a hand-calculator
48.62	17.28	
980.1	347.8	
2443.2	863.4	
3640.9	1280.8	
4785.1	1667.9	

Injector Carryover	
Peak Areas:	Observations:
0.564	Confirm calculation accuracy using a hand-calculator

Injector Linearity		
Inj Volume µL:	**Heights:**	**Observations:**
5 uL	24.35	**Confirm calculation accuracy using a hand-calculator**
25 uL	122.08	
50 uL	244.35	
75 uL	367.62	
100 uL	489.1	

Gradient Dwell Volume and Accuracy			
Uracil tR:	**0.47 min**		**Observations:**
Gadient Onset:	1.08 min		**Confirm calculation accuracy using a hand-calculator**
100% Height:	247.60		
A/B	24.3700	220.6000	
C/B	25.0500	223.1000	
D/B	25.3600	222.5000	

Wavelength Accuracy	
Enter the following values:	
Hox:	**Confirm wavelength difference between nominal and found.**
241, 278, 362,452, 641	
Caff:	
204, 273	

PROCEDURE:

S1	Instruction	Expected Result	Actual Result
1.	In Windows file explorer, verify that the spreadsheet template file is read-only.	Template file is read-only	File is read-only: ✓ ☑ Hardcopy Attached
2.	Open the template file in MS Excel	File opens	File opens: ✓ ☑ Hardcopy Attached
3.	Attempt to select a protected cell in each of the sheets all worksheets.	Protected cells are not selectable.	Protected cells are not selectable: ✓ ☑ Hardcopy Attached
4.	Enter test script data into the template. Verify that all results are accurate in each worksheet. Attempt to enter negative numeric values into area and height cells. Enter text data into cells.	All results are accurate Warning should be displayed, with data entry not allowed.	All results are accurate: ✓ ☑ Hardcopy Attached
5.	Generate and print the spreadsheet using the macro buttons. Perform for each version of Excel tested.	Spreadsheet prints properly, including the Certificate without errors.	Excel 2002 Prints OK? ✓ Excel 2010 Prints OK? ✓ ☑ Hardcopy Attached

Tested By: CJT	**Date:** 5/23/12

Testers Comments: no errors found. met all protocol specifications

Reviewed By: [signature]	**Date:** 6/22/12

Reviewers Comments:

REVIEWED ALL DATA. (OK) - ALL SCRIPTS MEET.
CONFIRMED PRINTOUT FOR EXCEL 2010 -OK
- SOFTWARE REV 7.07 COMPLETE

Appendix B:

Spreadsheet Template Printouts

CJT 5/23/12

HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

by Chemical Solutions
Copyright 2012

Company/Lab ID:	Company ID
	More ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012
Qualification Expiration Date:	4/30/2013

Performance Qualification Solution Information:

Certificate Lot No.	11209A
Soln Exp. (Month-Year):	Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	*Comments:*
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header Information will appear on every page.
SOP Reference	Enter SOP reference	
Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
Component:	*Serial No.*	*Comments:*
Pump	Enter module serial number	Comments, e.g. model number
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

CERTIFICATE OF QUALIFICATION FOR HPLC SYSTEM HPLC #

RESEARCH ONLY
RH 5/22/12

HPLC Performance Qualification Results Summary Table

EXCEL HAND CALCULATION CHECK

	Test Description:	Results / Range:	Specifications:	Meets/Fails?	Test Date:
Pump:					
	Maximum Flow Rate Error:	3.4%	+/- 5 %	MEETS	4/22/2012
	Flow Stability (Tr drift over 10 injections):	0.75%	≤1.0 %	MEETS	4/22/2012
	Maximum Gradient Delivery Error:	-0.9%	2%	MEETS	4/22/2012
	Gradient Dwell Volume:	1.22 mL	Record	NA	4/22/2012
Injector:					
	Precision (10 consecutive injections):	0.14 %RSD	≤1.0 %	MEETS	4/22/2012
	Autosampler Injection Volume Linearity:	R^2=1.0000 from 5 µL to 100 µL	≥0.998	MEETS	4/22/2012
	% Carryover of Autosampler:	0.012 %	≤0.10 %	MEETS	4/22/2012
	Refrigerated Autosampler Temperature:	4.5°C	min/max: 2°C /8°C	MEETS	4/22/2012
Detector:					
	Wavelength Accuracy - Holmium Oxide:	max. error 0 nm (241 - 641 nm)	+/- 3 nm	MEETS	4/22/2012
	Wavelength Accuracy - Caffeine:	max. error 1 nm (205 - 273 nm)	+/- 3 nm	MEETS	4/22/2012
	Detector Noise:	0.041 mAU	Record	NA	4/22/2012
	Detector Area Linearity:	R^2=0.9999 (1.8 to 1668 mAU)	≥0.999	MEETS	4/22/2012
	Dynamic Linear Dynamic Range:	1668 mAU with <5% Error	Record	NA	4/22/2012
Column Oven:					
	Temperature Accuracy:	max error 1.5°C (20 - 80°C)	+/- 5 °C	MEETS	4/22/2012
System Performance:					
	Extra-Column Band Broadening:	9 µL	Record	NA	4/22/2012
	System Sensitivity - Caffeine LOD:	0.20 ng Caffeine	Record	NA	4/22/2012

EXCEL 2002
HP 3050 PRINTER

CONCLUSION: System HPLC # MEETS Qualification Criteria

Comments: Example Test Data for typical HPLC UV detector qualification.

Performed By: _____ Reviewed/Approved By: _____

Date: _____ Date: _____

HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

by Chemical Solutions
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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	Comments:
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header information will appear on every page.
SOP Reference	Enter SOP reference	
Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
Component:	*Serial No.*	*Comments:*
Pump	Enter module serial number	Comments, e.g. model number
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

PRE-QUALIFICATION INSTRUMENT HARDWARE TESTS:

Flow Rate Qualification:

Performed 4/22/2012 by a volumetric procedure
Reference: LB# 1 p. 1

Nominal Flow Rate Setting:	Flow Rate Found:	Calculated Flow % Accuracy:	Calculated Flow % Error:	Flow Error Specification:	Conclusions of Flow Accuracy:
0.5 mL/min	0.50 mL/min	99.5 %	-0.5 %	+/- 5 %	MEETS
1.0 mL/min	0.99 mL/min	99.0 %	-1.0 %		MEETS
5.0 mL/min	5.17 mL/min	103.4 %	3.4 %		MEETS

Warnings: None

Column Oven Qualification:

Performed 4/22/2012 using Thermocouple/Thermometer
Model No: Cole Parmer DT-1 Digital Thermometer, SN: SNX

Nominal Temperature	Temperature Found:	Column Oven Temp Error deg C:	Column Oven Temperature Error Specification:	Conclusions of Oven Accuracy:
20 deg C	21 deg C	1 deg C	+/- 5 °C	MEETS
40 deg C	40 deg C	0 deg C		MEETS
60 deg C	60 deg C	0 deg C		MEETS
80 deg C	79 deg C	-2 deg C		MEETS

Refrigerated Autosampler Qualification:

Performed 4/22/2012 using Thermocouple/Thermometer
Model No: Cole Parmer DT-1 Digital Thermometer, SN: SNX

Nominal Temperature	Temperature Found:	AS Temp Deviation deg C:	AS Temp Error Specification:	Conclusions of AS Temp Acc:
4 deg C	4.5 deg C	0.5 deg C	min/max: 2°C /8°C	MEETS

SYSTEM SUITABILITY:

Performed 4/22/2012

Retention time, Efficiency and Resolution :

System Suitability Parameter:	Data obtained for Caffeine (peak #3):	Limits: Lower	Limits: Upper	Conclusion:
Retention Time	1.341 minutes	1.0	1.5	MEETS
Column Efficiency:	5440 theoretical plates	2,000	NA	MEETS
Rs to Prior Peak	7.5	≥2.0	NA	MEETS
Rs to Next Peak	5.7	≥2.0	NA	MEETS

HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

by Chemical Solutions
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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No.	11209A
Soln Exp. (Month-Year):	Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	*Comments:*
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header information will appear on every page.
SOP Reference	Enter SOP reference	
Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
Component:	*Serial No.*	*Comments:*
Pump	Enter module serial number	Comments, e.g. model number
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

ASTM Detector Dynamic Short-Term Noise:

Performed 4/22/2012

File# used for evaluation:	001-0102	
Detector/Data System Time Constant:	0.032	
Peak-Peak Noise:	0.041	mAU @ 273 nm

Acceptance Limit for Noise: Record

Conclusions of Noise Determination: RECORD

HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

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Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

HPLC Extra-Column Volume:

Performed 4/22/2012

Efficiency Method Used: Half Height

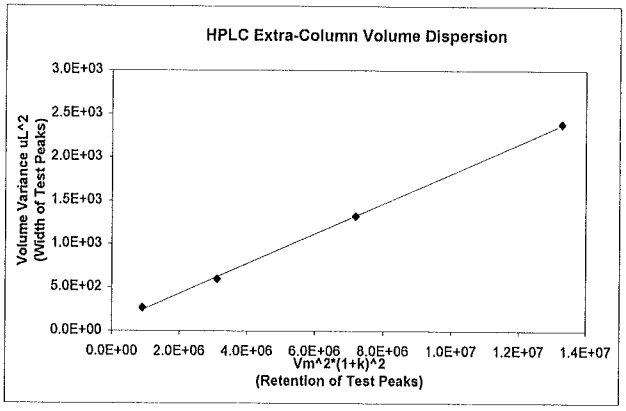
Compound:	*Retention Time (minutes):*	*System Efficiency N:*
Peak 1 (t0):	0.476	3415
Peak 2:	0.883	5230
Peak 3:	1.341	5440
Peak 4:	1.823	5570

HPLC EC Volume (Bandwidth):	9 µL
Dispersion Index (EC Volume Variance):	85 µL^2
True column efficiency:	5793 plates
Column reduced h:	2.6

Typical Extra-Column (EC) Dispersion Values: <10uL = low EC volume
11-49 uL = Moderate EC Volume
>50uL = Excessive EC Volume

Acceptance Limit HPLC Extra Column Volume: Record

Conclusions of HPLC Extra Column Volume: RECORD



CS 5/23/12

HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A / Dec-2013
Solution	**Concentration**
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HPLC Instrumentation Information:

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Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

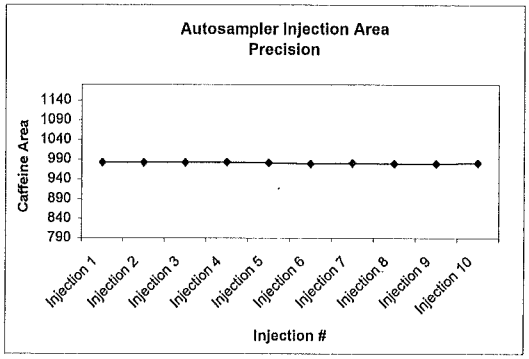
Autosampler Injection Precision and Pump Stability:

Performed 4/22/2012

Solution Used:	Injection Volume:
L3	8 uL

Injection #:	Ret. Time min.	Caffeine Area
Injection 1	1.334	982.60
Injection 2	1.333	983.10
Injection 3	1.332	983.20
Injection 4	1.331	983.40
Injection 5	1.328	981.80
Injection 6	1.327	979.80
Injection 7	1.326	981.20
Injection 8	1.325	980.10
Injection 9	1.325	979.90
Injection 10	1.324	981.30
Average:	1.329	981.64
Minimum:	1.324	979.80
Maximum:	1.334	983.40
Std. Dev.	0.004	1.403
Autosampler Injection Precision- Min as % of Avg		-0.19 %
Max as % of Avg:		0.18 %
% Spread (Max-Min/Mean*100):		0.37 %
%RSD (Coefficient of Variation):		0.14 %

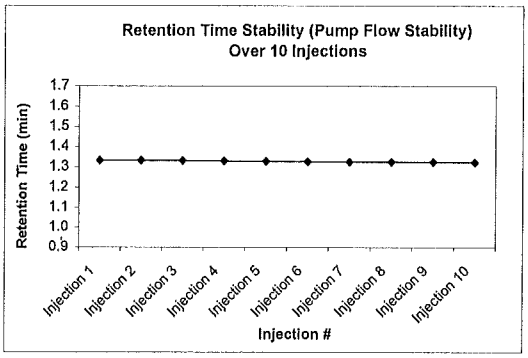
Acceptance Limit for Area Precision:	≤1.0 %RSD
Conclusions of Autosampler Precision:	MEETS



Retention Time (Flow Rate) Stability:

Min as % of Avg:	-0.34%
Max as % of Avg:	0.41%
Flow Drift:	0.75%
%RSD:	0.28 %

Acceptance Limit for Flow Rate Drift ((Max - Min)/Avg):	≤1.0 %
Conclusions of Flow Rate Drift:	MEETS



HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

by Chemical Solutions
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Company/Lab ID: Company ID
Analyst: analyst

Date Qualification Started: 4/22/2012
Date Qualification Completed: 4/22/2012

Performance Qualification Solution Information:

Certificate Lot No.	11209A
Soln Exp. (Month-Year):	Dec-2013
Solution	**Concentration**
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Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

Detector Response Linearity:

Performed 4/22/2012

Injection Volume Used for Linearity: 8 uL

Solution:	Conc (mg/mL) (from PQ Kit CoA)	Peak Area:	Area Residuals	Peak Height (mAU)	Height Residuals
L1 (0.1%)	0.0003500	4.33	-13.07	1.76	-7.64
L2 (1.0%)	0.003500	48.62	-12.00	17.28	-7.23
L3 (20%)	0.07000	980.10	6.94	347.80	4.42
L4 (50%)	0.1750	2443.20	29.18	863.40	16.55
L5 (75%)	0.2630	3640.90	19.30	1280.80	11.98
L6 (100%)	0.3500	4785.10	-30.35	1667.90	-18.08

Linearity Results Summary

	Peak Area:	Peak Height:
Slope:	13722.44	4795.02
Intercept:	12.59 ±42.07 @ 95% CI	7.72 ±24.84 @ 95% CI
R:	0.99994	0.99982
R^2:	0.99987	0.99963
Acceptance Limit for R^2 (Area):	≥0.999	

Conclusions of Detector Area Linearity @ 273 nm: MEETS

NOTE: Detector Linearity graph autoscales - Residuals graph (below) must be manually re-scaled on Y axis to show desired level of detail. Right click on Y-axis and click on "Format Axis" set scale to encompass residuals values from results above.

Detector Sensitivity Results Summary

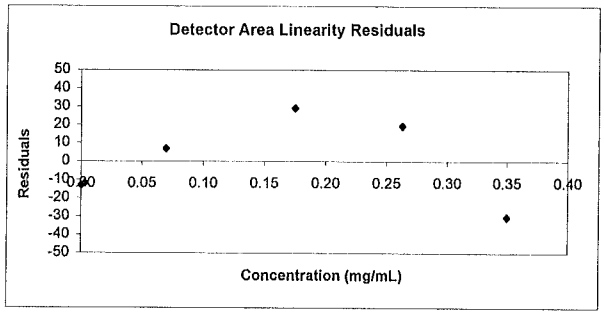
Detector Sensitivity and Detectability for Caffeine @ 273 nm	
S/N for L1	42.9
System Sensitivity	599.4 mAu/µg
LOD @ S/N = 3 for Caffeine	0.20 ng Caffeine

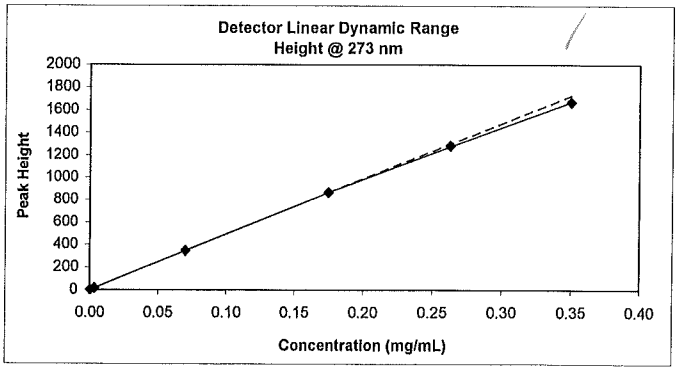
Acceptance Limit for LOD: Record

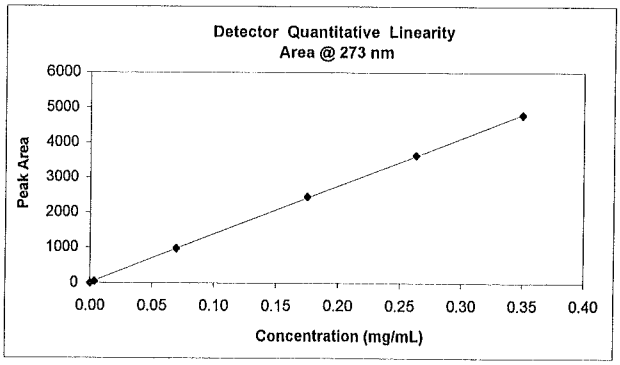
Conclusions for Detector Sensitivity: RECORD

Dynamic Linear Range (Based on Peak Heights)

Conclusions: Detector is linear to 1668 mAU with <5% Error







HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

by Chemical Solutions
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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	*Comments:*
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header information will appear on every page.
SOP Reference	Enter SOP reference	
Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
Component:	*Serial No.*	*Comments:*
Pump	Enter module serial number	Comments, e.g. model number
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

Injector Carryover:

Performed 4/22/2012

Area of L6 Solution (from Linearity): 4785.10

	Area:	% Carryover:
MP Blank Area @Caffeine tR: 1st Blank Injection - For %Carryover:	0.564	0.012%

Carry-Over Test Conditions:	
Needle-Wash? (Y/N):	No Wash

Acceptance Criteria: ≤0.10 %

Conclusions of Autosampler Carry-Over: MEETS

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Company/Lab ID: Company ID
Analyst: analyst

Date Qualification Started: 4/22/2012
Date Qualification Completed: 4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A / Dec-2013
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Serial No:	M10-ST09-xxx
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Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

Autosampler Injection Volume Linearity:

Performed 4/22/2012

Linearity Solution Used: L2
Concentration: 0.0035 mg/mL

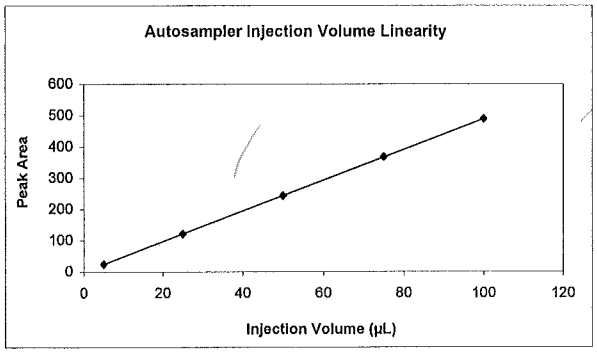
Injection Volume uL:	*Peak Area*	*Avg. Response Factors*	*Residuals Values*	*Delivered Accuracy as % of 2nd Inj Vol*
5 uL	24.35	34786	0.07	99.7%
25 uL	122.08	34880	-0.12	100.0 %
50 uL	244.35	34907	-0.25	100.1%
75 uL	367.62	35011	0.61	100.4%
100 uL	489.10	34936	-0.31	100.2%

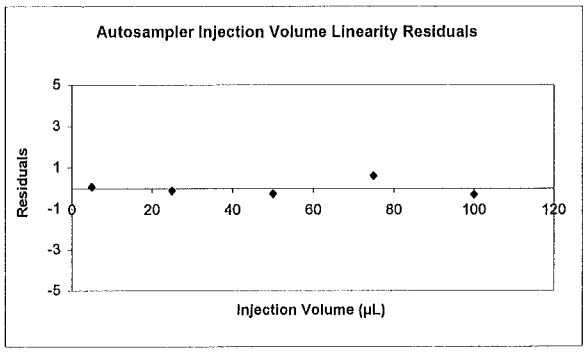
Slope: 4.896
Intercept: -0.20 ±1.11 @ 95% CI
R: 1.00000
R^2: 1.00000
Acceptance Limit for R^2: ≥0.998

(Note: If these results will not calculate, and all concentrations and areas are filled in, check that the MS Excel Analysis Tool Pack is loaded, in the Tools menu, under Add-ins...)

Conclusions of Injection Volume Linearity: MEETS

NOTE: Volume Linearity graph autoscales - Residuals graph (below) must be manually re-scaled on Y axis to show desired level of detail. Right click on Y-axis and click on "Format Axis" set scale to encompass residuals values from results above.





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Company/Lab ID:	Company ID	Date Qualification Started:	4/22/2012
Analyst:	analyst	Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No.	11209A
Soln Exp. (Month-Year):	Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	Comments:
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header information will appear on every page.
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Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
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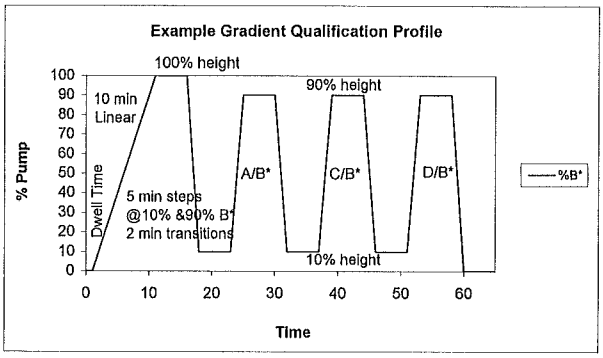
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

HPLC Gradient Accuracy and Dwell Volume:

Performed 4/22/2012

GRADIENT DWELL VOLUME:

Retention Time of Uracil	0.47 min
Apparent Time of gradient onset	1.08 min
Gradient Dwell Volume:	1.22 mL
Acceptance Limit Gradient Dwell Volume:	Record
Conclusions of Gradient Dwell Volume:	RECORD



GRADIENT ACCURACY:

Pump/Solenoid Combination:	Heights of Gradient Steps at nominal solvent deliveries of 10% and 90%		
100% B* Height:	247.60		mAU
	10%	90%	Height Units
Combination A/B*	24.37	220.60	mAU
Combination C/B*	25.05	223.10	mAU
Combination D/B*	25.36	222.50	mAU

Solvent Delivery Acceptance Criteria for Each Gradient Step:

% Delivery Error Specification:
2 %

	% Delivery and %Error				
Solenoid in Pump/Solenoid Combination	10% B		90% B		Conclusions
Solenoid A in Combination A/B*	9.8%B Delivered	-0.2% Error	89.1%B Delivered	-0.9% Error	MEETS
Solenoid C in Combination C/B*	10.1%B Delivered	0.1% Error	90.1%B Delivered	0.1% Error	MEETS
Solenoid D in Combination D/B*	10.2%B Delivered	0.2% Error	89.9%B Delivered	-0.1% Error	MEETS

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4/22/2012

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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A / Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

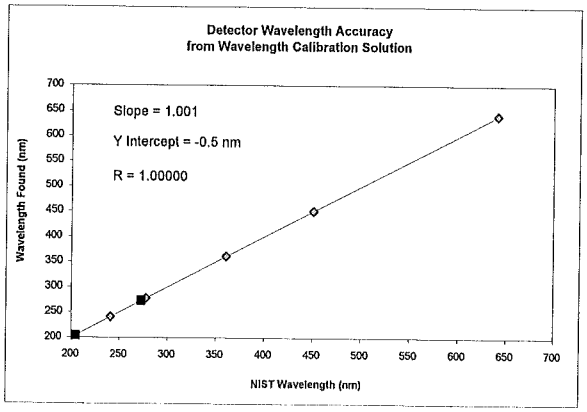
System Identifier	HPLC #	*Comments:*
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header Information will appear on every page.
SOP Reference	Enter SOP reference	
Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
Component:	*Serial No.*	*Comments:*
Pump	Enter module serial number	Comments, e.g. model number
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

Detector Wavelength Accuracy - Primary Standard (Holmium Oxide) and Secondary Standard (Caffeine):

Performed 4/22/2012

Nominal NIST Wavelength (nm)	Wavelength Found (nm)	Error (nm)	Method Used
241 nm	241 nm	0	DAD
278 nm	278 nm	0	DAD
361 nm	361 nm	0	DAD
451 nm	451 nm	0	DAD
641 nm	641 nm	0	DAD
Nominal Caffeine Wavelength (nm)	**Wavelength Found (nm)**	**Error (nm)**	**Method Used**
205 nm	204 nm	1	DAD
273 nm	273 nm	0	DAD

Wavelength Regression Results: Slope = 1.001; Y Intercept = -0.5 nm; R = 1.00000



Bandwidth (nm):	8
Slit Width (nm):	0 nm
Enter Acceptance Limit +/- nm:	3 nm
Conclusions of Wavelength Accuracy:	MEETS

Acceptance Criteria:
Consult instrument manual
Set at +/- 1/2 of Bandwidth if known
or +/- 3 nm as per proposed USP specs
(see USP Forum Vol 31(6), Nov-Dec 2005, p. 1685)

FYI Only: Extrapolation of Wavelength Accuracy to Spectral Limits 200 - 700 nm

Extrapolated Wavelength Accuracy:	Extrapolated Wavelength:	Extrapolated Error nm
Expected Accuracy @ 200 nm:	200	0 nm
Expected Accuracy @ 360 nm:	360	0 nm
Expected Accuracy @ 700 nm:	700	0 nm

HPLC Performance Qualification System - High Speed

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4/22/2012

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Company/Lab ID:	Company ID
	More ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012
Qualification Expiration Date:	*4/30/2013*

Performance Qualification Solution Information:

Certificate Lot No.	11209A
Soln Exp. (Month-Year):	Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	*Comments:*
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header information will appear on every page.
SOP Reference	Enter SOP reference	
Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
Component:	*Serial No.*	*Comments:*
Pump	Enter module serial number	Comments, e.g. model number
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

CERTIFICATE OF QUALIFICATION FOR HPLC SYSTEM HPLC #

RESEARCH ONLY

HPLC Performance Qualification Results Summary Table

	Test Description:	Results / Range:	Specifications:	Meets/Falls?	Test Date:
Pump:					
	Maximum Flow Rate Error:	3.4%	+/- 5 %	MEETS	4/22/2012
	Flow Stability (Tr drift over 10 injections):	0.75%	≤1.0 %	MEETS	4/22/2012
	Maximum Gradient Delivery Error:	-0.9%	2%	MEETS	4/22/2012
	Gradient Dwell Volume:	1.22 mL	Record	NA	4/22/2012
Injector:					
	Precision (10 consecutive injections):	0.14 %RSD	≤1.0 %	MEETS	4/22/2012
	Autosampler Injection Volume Linearity:	R^2=1.0000 from 5 µL to 100 µL	≥0.998	MEETS	4/22/2012
	% Carryover of Autosampler:	0.012 %	≤0.10 %	MEETS	4/22/2012
	Refrigerated Autosampler Temperature:	4.5°C	min/max: 2°C /8°C	MEETS	4/22/2012
Detector:					
	Wavelength Accuracy - Holmium Oxide:	max. error 0 nm (241 - 641 nm)	+/- 3 nm	MEETS	4/22/2012
	Wavelength Accuracy - Caffeine:	max. error 1 nm (205 - 273 nm)	+/- 3 nm	MEETS	4/22/2012
	Detector Noise:	0.041 mAU	Record	NA	4/22/2012
	Detector Area Linearity:	R^2=0.9999 (1.8 to 1668 mAU)	≥0.999	MEETS	4/22/2012
	Dynamic Linear Dynamic Range:	1668 mAU with <5% Error	Record	NA	4/22/2012
Column Oven:					
	Temperature Accuracy:	max error 1.5°C (20 - 80°C)	+/- 5 °C	MEETS	4/22/2012
System Performance:					
	Extra-Column Band Broadening:	9 µL	Record	NA	4/22/2012
	System Sensitivity - Caffeine LOD:	0.20 ng Caffeine	Record	NA	4/22/2012

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BW 6/22/12
HP 3050 PRINTER
OK
PRINT CHECK ONLY

CONCLUSION: System HPLC # MEETS Qualification Criteria

Comments: Example Test Data for typical HPLC UV detector qualification.

Performed By: _____ Reviewed/Approved By: _____

Date: _____ Date: _____

HPLC Performance Qualification System - High Speed

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4/22/2012

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Company/Lab ID:	Company ID	Date Qualification Started:	4/22/2012
Analyst:	analyst	Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No.	11209A
Soln Exp. (Month-Year):	Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	Comments:
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header Information will appear on every page.
SOP Reference	Enter SOP reference	
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Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

PRE-QUALIFICATION INSTRUMENT HARDWARE TESTS:

Flow Rate Qualification:

Performed 4/22/2012 by a volumetric procedure
Reference: LB# 1 p. 1

Nominal Flow Rate Setting:	*Flow Rate Found:*	*Calculated Flow % Accuracy:*	*Calculated Flow % Error:*	*Flow Error Specification:*	*Conclusions of Flow Accuracy:*
0.5 mL/min	0.50 mL/min	99.5 %	-0.5 %	+/- 5 %	MEETS
1.0 mL/min	0.99 mL/min	99.0 %	-1.0 %		MEETS
5.0 mL/min	5.17 mL/min	103.4 %	3.4 %		MEETS

Warnings: None

Column Oven Qualification:

Performed 4/22/2012 using Thermocouple/Thermometer
Model No: Cole Parmer DT-1 Digital Thermometer, SN: SNX

Nominal Temperature	*Temperature Found:*	*Column Oven Temp Error deg C:*	*Column Oven Temperature Error Specification:*	*Conclusions of Oven Accuracy:*
20 deg C	21 deg C	1 deg C	+/- 5 °C	MEETS
40 deg C	40 deg C	0 deg C		MEETS
60 deg C	60 deg C	0 deg C		MEETS
80 deg C	79 deg C	-2 deg C		MEETS

Refrigerated Autosampler Qualification:

Performed 4/22/2012 using Thermocouple/Thermometer
Model No: , SN: SNXXXX,

Nominal Temperature	*Temperature Found:*	*AS Temp Deviation deg C:*	*AS Temp Error Specification:*	*Conclusions of AS Temp Acc:*
4 deg C	4.5 deg C	0.5 deg C	min/max: 2°C /8°C	MEETS

SYSTEM SUITABILITY:

Performed 4/22/2012

Retention time, Efficiency and Resolution :

System Suitability Parameter:	Data obtained for Caffeine (peak #3):	Limits: Lower	Limits: Upper	Conclusion:
Retention Time	1.341 minutes	1.0	1.5	MEETS
Column Efficiency:	5440 theoretical plates	2,000	NA	MEETS
Rs to Prior Peak	7.5	≥2.0	NA	MEETS
Rs to Next Peak	5.7	≥2.0	NA	MEETS

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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
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Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A / Dec-2013
Solution	**Concentration**
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Linearity Solution L6	0.3500 mg/mL
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Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	*Comments:*
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Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

ASTM Detector Dynamic Short-Term Noise:

Performed 4/22/2012

File# used for evaluation:	001-0102	
Detector/Data System Time Constant:	0.032	
Peak-Peak Noise:	0.041	mAU @ 273 nm

Acceptance Limit for Noise: Record

Conclusions of Noise Determination: RECORD

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4/22/2012

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Analyst:	analyst

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Performance Qualification Solution Information:

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Detector	Enter module serial number	
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Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

HPLC Extra-Column Volume:

Performed 4/22/2012

Efficiency Method Used: Half Height

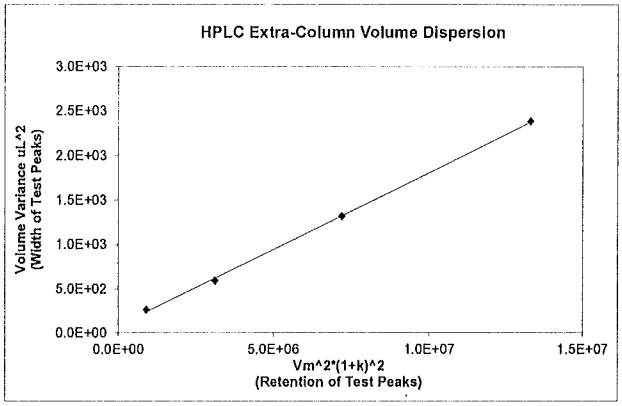
Compound:	Retention Time (minutes):	System Efficiency N:
Peak 1 (t0):	0.476	3415
Peak 2:	0.883	5230
Peak 3:	1.341	5440
Peak 4:	1.823	5570

HPLC EC Volume (Bandwidth):	9 µL
Dispersion Index (EC Volume Variance):	85 µL^2
True column efficiency:	5793 plates
Column reduced h:	2.6

Typical Extra-Column (EC) Dispersion Values: <10uL = low EC volume
11-49 uL = Moderate EC Volume
>50uL = Excessive EC Volume

Acceptance Limit HPLC Extra Column Volume: Record

Conclusions of HPLC Extra Column Volume: RECORD



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Company/Lab ID: Company ID
Analyst: analyst

Date Qualification Started: 4/22/2012
Date Qualification Completed: 4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A Dec-2013
Solution	**Concentration**
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Linearity Solution L4	0.1750 mg/mL
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Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
Component:	*Serial No.*	*Comments:*
Pump	Enter module serial number	Comments, e.g. model number
Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

Autosampler Injection Precision and Pump Stability:

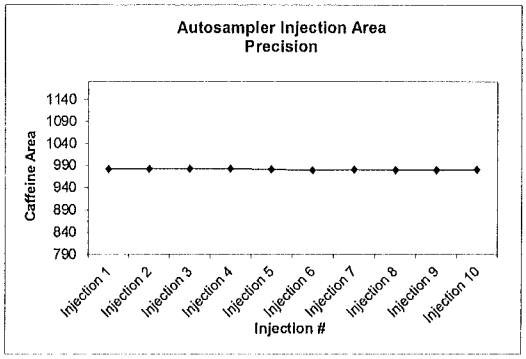
Performed 4/22/2012

Solution Used:	Injection Volume:
L3	8 uL

Injection #:	Ret. Time min.	Caffeine Area
Injection 1	1.334	982.60
Injection 2	1.333	983.10
Injection 3	1.332	983.20
Injection 4	1.331	983.40
Injection 5	1.328	981.80
Injection 6	1.327	979.80
Injection 7	1.326	981.20
Injection 8	1.325	980.10
Injection 9	1.325	979.90
Injection 10	1.324	981.30
Average:	**1.329**	**981.64**
Minimum:	1.324	979.80
Maximum:	1.334	983.40
Std. Dev.	0.004	1.403

Autosampler Injection Precision- Min as % of Avg:	-0.19 %
Max as % of Avg:	0.18 %
% Spread (Max-Min/Mean*100):	0.37 %
%RSD (Coefficient of Variation):	**0.14 %**

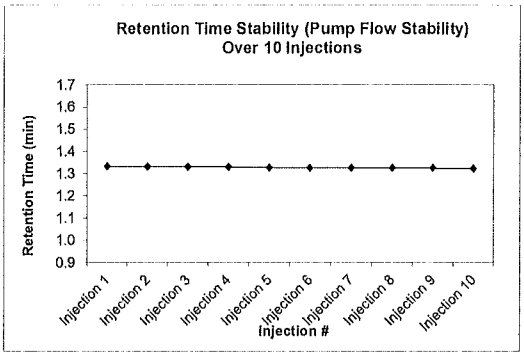
Acceptance Limit for Area Precision:	**≤1.0 %RSD**
Conclusions of Autosampler Precision:	MEETS



Retention Time (Flow Rate) Stability:

Min as % of Avg:	-0.34%
Max as % of Avg:	0.41%
Flow Drift:	**0.75%**
%RSD:	0.28 %

Acceptance Limit for Flow Rate Drift ((Max - Min)/Avg):	**≤1.0 %**
Conclusions of Flow Rate Drift:	MEETS



HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

by Chemical Solutions
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Company/Lab ID: Company ID
Analyst: analyst

Date Qualification Started: 4/22/2012
Date Qualification Completed: 4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
Linearity Solution L4	0.1750 mg/mL
Linearity Solution L5	0.2630 mg/mL
Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	*Comments:*
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header information will appear on every page.
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Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

Detector Response Linearity:

Performed 4/22/2012

Injection Volume Used for Linearity: 8 uL

Solution:	*Conc (mg/mL) (from PQ Kit CoA)*	*Peak Area:*	*Area Residuals*	*Peak Height (mAU)*	*Height Residuals*
L1 (0.1%)	0.0003500	4.33	-13.07	1.76	-7.64
L2 (1.0%)	0.003500	48.62	-12.00	17.28	-7.23
L3 (20%)	0.07000	980.10	6.94	347.80	4.42
L4 (50%)	0.1750	2443.20	29.18	863.40	16.55
L5 (75%)	0.2630	3640.90	19.30	1280.80	11.98
L6 (100%)	0.3500	4785.10	-30.35	1667.90	-18.08

Linearity Results Summary

	Peak Area:	Peak Height:
Slope:	13722.44	4795.02
Intercept:	12.59 ±42.07 @ 95% CI	7.72 ±24.84 @ 95% CI
R:	0.99994	0.99982
R^2:	0.99987	0.99963
Acceptance Limit for R^2 (Area):	≥0.999	

Conclusions of Detector Area Linearity @ 273 nm: MEETS

NOTE: Detector Linearity graph autoscales - Residuals graph (below) must be manually re-scaled on Y axis to show desired level of detail. Right click on Y-axis and click on "Format Axis" set scale to encompass residuals values from results above.

Detector Sensitivity Results Summary

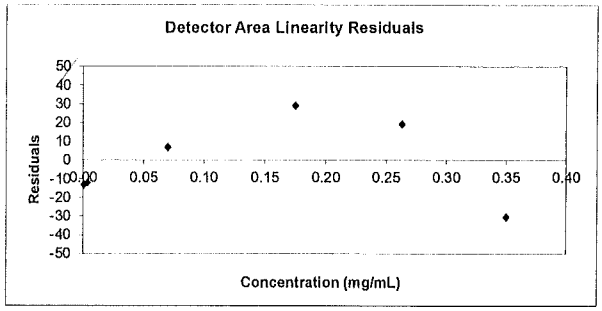
Detector Sensitivity and Detectability for Caffeine @ 273 nm	
S/N for L1	42.9
System Sensitivity	599.4 mAu/µg
LOD @ S/N = 3 for Caffeine	0.20 ng Caffeine

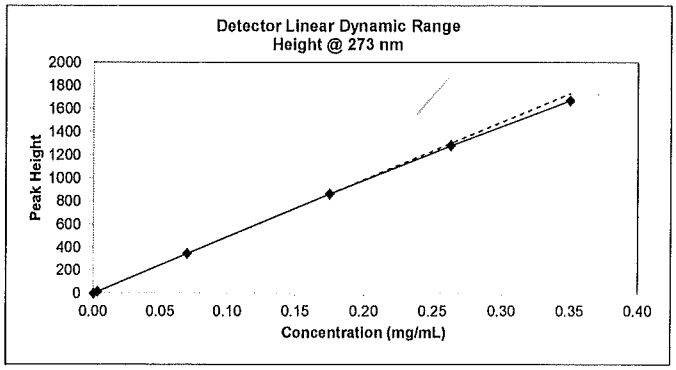
Acceptance Limit for LOD: Record

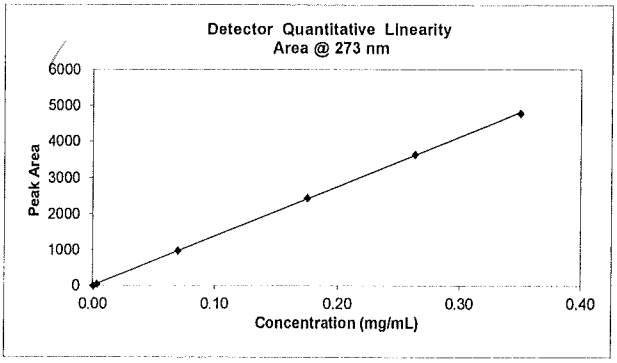
Conclusions for Detector Sensitivity: RECORD

Dynamic Linear Range (Based on Peak Heights)

Conclusions: Detector is linear to 1668 mAU with <5% Error







HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

by Chemical Solutions
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Company/Lab ID:	Company ID
Analyst:	analyst

Date Qualification Started:	4/22/2012
Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A Dec-2013
Solution	**Concentration**
Linearity Solution L1	0.0003500 mg/mL
Linearity Solution L2	0.003500 mg/mL
Linearity Solution L3	0.07000 mg/mL
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Linearity Solution L6	0.3500 mg/mL
PQ Test Column: C8 (USP L7) Packing	
Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
Internal Diameter (mm):	4.6 mm
Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

System Identifier	HPLC #	*Comments:*
Project No.	Enter Project Number	Enter any comments about the qualification here if desired. Header information will appear on every page.
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Logbook Ref	Enter any logbook reference	
Seq No.	Enter any sequence references	
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Detector	Enter module serial number	
Autosampler	Enter module serial number	
Column Oven	Enter module serial number	
Degasser	Enter module serial number	
Enter Others	add or delete components	
	to describe your system.	

Injector Carryover:

Performed 4/22/2012

Area of L6 Solution (from Linearity): 4785.10

MP Blank Area @Caffeine tR:	Area:	% Carryover:
1st Blank Injection - For %Carryover:	0.564	0.012%

Carry-Over Test Conditions:	
Needle-Wash? (Y/N):	No Wash

Acceptance Criteria: ≤0.10 %

Conclusions of Autosampler Carry-Over: MEETS

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Company/Lab ID: Company ID
Analyst: analyst

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Enter Others	add or delete components	
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Autosampler Injection Volume Linearity:

Performed 4/22/2012

Linearity Solution Used: L2
Concentration: 0.0035 mg/mL

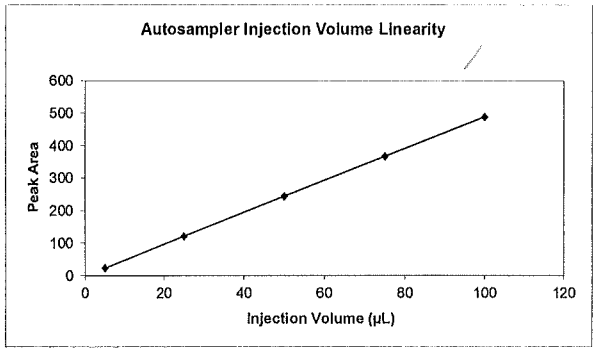
Injection Volume uL:	*Peak Area*	*Avg. Response Factors*	*Residuals Values*	*Delivered Accuracy as % of 2nd Inj Vol*
5 uL	24.35	34786	0.07	99.7%
25 uL	122.08	34880	-0.12	100.0 %
50 uL	244.35	34907	-0.25	100.1%
75 uL	367.62	35011	0.61	100.4%
100 uL	489.10	34936	-0.31	100.2%

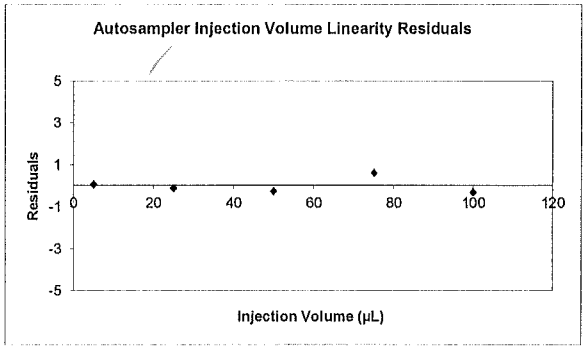
Slope: 4.896
Intercept: -0.20 ±1.11 @ 95% CI
R: 1.00000
R^2: 1.00000
Acceptance Limit for R^2: ≥0.998

(Note: If these results will not calculate, and all concentrations and areas are filled in, check that the MS Excel Analysis Tool Pack is loaded, in the Tools menu, under Add-ins...)

Conclusions of Injection Volume Linearity: MEETS

NOTE: Volume Linearity graph autoscales - Residuals graph (below) must be manually re-scaled on Y axis to show desired level of detail. Right click on Y-axis and click on "Format Axis" set scale to encompass residuals values from results above.





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Company/Lab ID:	Company ID
Analyst:	analyst
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Certificate Lot No. / Soln Exp. (Month-Year):	11209A / Dec-2013
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Particle Size (µm):	5 µm

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Enter Others	add or delete components	
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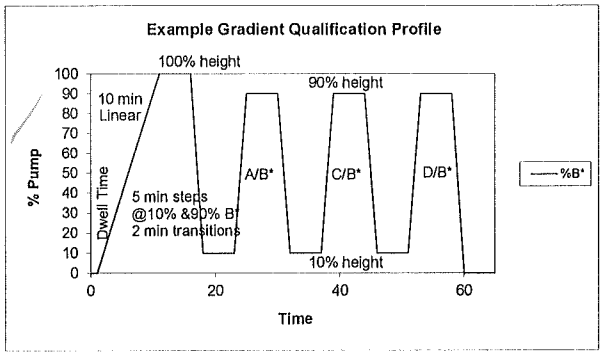
HPLC Gradient Accuracy and Dwell Volume:

Performed 4/22/2012

GRADIENT DWELL VOLUME:

Retention Time of Uracil:	0.47 min
Apparent Time of gradient onset:	1.08 min
Gradient Dwell Volume:	1.22 mL
Acceptance Limit Gradient Dwell Volume:	Record
Conclusions of Gradient Dwell Volume:	RECORD



GRADIENT ACCURACY:

Pump/Solenoid Combination:	Heights of Gradient Steps at nominal solvent deliveries of 10% and 90%		
100% B* Height:	247.60		mAU
	10%	90%	Height Units
Combination A/B*	24.37	220.60	mAU
Combination C/B*	25.05	223.10	mAU
Combination D/B*	25.36	222.50	mAU

Solvent Delivery Acceptance Criteria for Each Gradient Step:

% Delivery Error Specification:
2 %

	% Delivery and %Error				
Solenoid in Pump/Solenoid Combination	10% B		90% B		Conclusions
Solenoid A in Combination A/B*	9.8%B Delivered	-0.2% Error	89.1%B Delivered	-0.9% Error	MEETS
Solenoid C in Combination C/B*	10.1%B Delivered	0.1% Error	90.1%B Delivered	0.1% Error	MEETS
Solenoid D in Combination D/B*	10.2%B Delivered	0.2% Error	89.9%B Delivered	-0.1% Error	MEETS

HPLC Performance Qualification System - High Speed

rev 7.07
4/22/2012

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Company/Lab ID:	Company ID	Date Qualification Started:	4/22/2012
Analyst:	analyst	Date Qualification Completed:	4/22/2012

Performance Qualification Solution Information:

Certificate Lot No. / Soln Exp. (Month-Year):	11209A / Dec-2013
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Item No:	75008-7.5P
Serial No:	M10-ST09-xxx
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Length (mm):	75 mm
Particle Size (µm):	5 µm

HPLC Instrumentation Information:

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Column Oven	Enter module serial number	
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Enter Others	add or delete components	
	to describe your system.	

Detector Wavelength Accuracy - Primary Standard (Holmium Oxide) and Secondary Standard (Caffeine):

Performed 4/22/2012

Nominal NIST Wavelength (nm)	Wavelength Found (nm)	Error (nm)	Method Used
241 nm	241 nm	0	DAD
278 nm	278 nm	0	DAD
361 nm	361 nm	0	DAD
451 nm	451 nm	0	DAD
641 nm	641 nm	0	DAD
Nominal Caffeine Wavelength (nm)	**Wavelength Found (nm)**	**Error (nm)**	**Method Used**
205 nm	204 nm	1	DAD
273 nm	273 nm	0	DAD

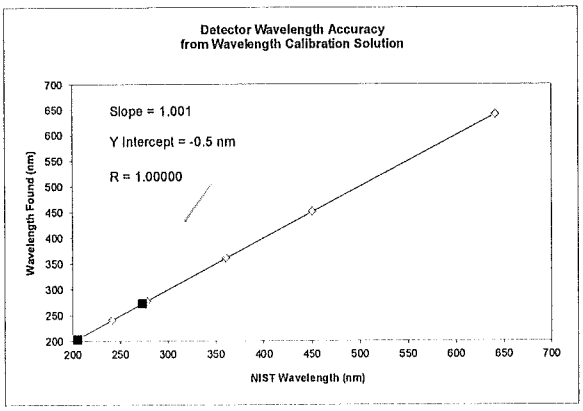
Wavelength Regression Results: Slope = 1.001; Y Intercept = -0.5 nm; R = 1.00000

Bandwidth (nm): 8
Slit Width (nm): 0 nm

Enter Acceptance Limit +/- nm: 3 nm

Conclusions of Wavelength Accuracy: **MEETS**

Acceptance Criteria:
Consult instrument manual
Set at +/- 1/2 of Bandwidth if known
or +/- 3 nm as per proposed USP specs
(see USP Forum Vol 31(6), Nov-Dec 2005, p. 1685)



FYI Only: Extrapolation of Wavelength Accuracy to Spectral Limits 200 - 700 nm

Extrapolated Wavelength Accuracy:	Extrapolated Wavelength:	Extrapolated Error nm
Expected Accuracy @ 200 nm:	200	0 nm
Expected Accuracy @ 360 nm:	360	0 nm
Expected Accuracy @ 700 nm:	700	0 nm