

IQ / OQ / PQ

Laboratory Instrument Validation
Performed and Documented in GLP Format

HPLC & LC Systems

Biomatic Technologies

OQ - Operational Qualification

HPLC & LC Systems

- Temperature accuracy and stability of column heater/cooler
- Holmium Oxide wavelength scan (if applicable)
- Detector lamp intensity, and wavelength accuracy
- Detector Noise and Drift
- Pump flow rate accuracy and repeatability
- High and low pressure shutdown accuracy
- Injector precision

Five repeated injections of standard caffeine sample
Compare area count and retention time deviations

- Detector linearity and sample-to-sample carryover

Five injections of increasing concentration standard caffeine samples, followed by HPLC water injection
Compare linearity of area counts, and check for carryover in water blank

- Injection volume linearity

5, 10, 20, 40, and 60 ul injections of standard caffeine sample
Compare linearity of area counts

- Gradient composition accuracy

Linear gradient tested using IPA and 0.5% Acetone/IPA
Five step gradient tested using IPA and 0.5% Acetone/IPA

IQ - Installation Qualification

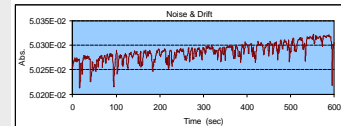
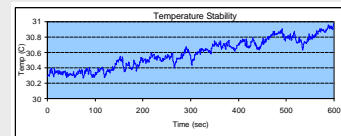
- Inventory of instruction manuals, components and serial numbers
- Installation verification

PQ - Performance Qualification

System performance and robustness

- Typically a 5 or 10 ul injection of a low concentration sample, repeated five times.
- Compare area count and retention time deviations

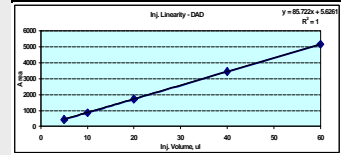
Data Analysis of Test Results Graphical Display & Charts



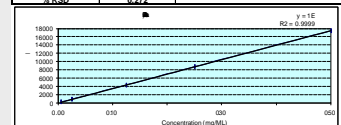
Set Temperature	30 C	Noise	3.54E-04 AU
Observed	30.58	Drift	4.78E-05 AU/Hour
%RSD	0.19		

Injection Precision Test - HPLC System - DAD			
10 ul injection from 0.125 mg/mL Caffeine			
Run #	Retention Time, min	Peak Area	Peak Height
1	3.69	4310.75	186.98
2	3.67	4324.67	188.33
3	3.69	4323.02	187.96
4	3.70	4326.53	187.44
5	3.70	4318.45	187.19
Average	3.68	4323.17	187.73
Average Deviation	0.01	2.43	0.42
% RSD	0.39	0.06	0.22

Injector Linearity Test - HPLC System - DAD			
Injection of Caffeine standard solution, 0.025 mg/mL			
Run #	Retention Time, min	Injection Volume, ul	Peak Area
1	3.74	5	432.76
2	3.74	10	867.2
3	3.75	20	1716.49
4	3.78	40	3434.85
5	3.80	60	5149.32
Average	3.76		
Average Deviation	0.02		
%RSD	0.63		



Detector Absorbance Linearity Test - DAD			
10 ul injection of Caffeine standard solution			
Injection #	Retention Time, min	Peak Area	Caffeine Concentration, mg/mL
1	3.76	18.05	0.0050
2	3.74	856.51	0.0250
3	3.73	4313.17	0.1250
4	3.73	8705.65	0.2500
5	3.75	17498.80	0.5000
Average	3.75		
Average Deviation	0.019		
% RSD	0.474		



Biomatic Technologies Specialties

- Reconditioned Lab Equipment
- Service & Maintenance of Lab Equipment
 - Instrument IQ, OQ, PQ Validation
 - Asset Management & Inventory Control
 - Contract R & D and Consulting

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