

IQ / OQ / PQ

Laboratory Instrument Validation
Performed and Documented in GLP Format

GC Systems

Biomatic Technologies

OQ - Operational Qualification

GC Systems (FID, NPD, ECD, FPD, TCD)

- Temperature accuracy and stability

Oven set to 50, 150, 200, 250, and 300 degrees Celsius and temperature measured with calibrated thermocouples for accuracy and stability

- Temperature uniformity

Oven temperature is measured at the top, middle, and bottom levels with calibrated thermocouples for uniformity

- Injector and detector temperature accuracy
- Detector noise and drift
- Gas flow rate accuracy and split flow ratio
- Injection precision

Five repeated injections of standard 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.

IQ - Installation Qualification

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

PQ - Performance Qualification

- System performance and robustness

Typically an injection of a low concentration sample, repeated five times.
Compare area count and retention time deviations

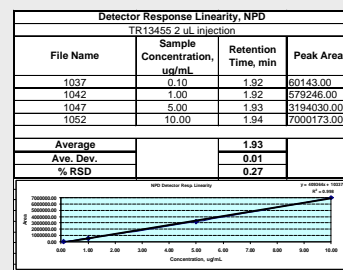
- Data analysis verification

Data Analysis of Test Results Graphical Display & Charts

Oven Temperature Accuracy and Stability, GC System					
Set Temperature, C	50.00	150.00	200.00	250.00	300.00
Average	50.29	152.91	201.36	253.80	304.38
Average Dev.	0.05	0.11	0.04	0.13	0.16
% RSD	0.11	0.07	0.02	0.05	0.05
Maximum	50.45	153.23	201.52	254.23	304.96
Minimum	50.17	152.68	201.22	253.49	304.01

Oven Temperature Uniformity, GC System			
Set Temperature, C	200.00		
	Top	Middle	Bottom
Average	203.12	201.36	201.62
Average Dev.	0.09	0.04	0.06
% RSD	0.04	0.02	0.03
Maximum	203.41	201.52	201.81
Minimum	202.92	201.22	201.39

Injection Precision, NPD		
TR13455 1 ug/mL, 2uL injection		
Run #	Retention Time, min	Peak Area
1	1.92	579245.00
2	1.93	572466.00
3	1.93	570259.00
4	1.93	570863.00
5	1.93	574239.00
Average	1.93	573414.40
Ave. Dev.	0.00	2662.08
% RSD	0.04	0.46



Performance Qualification, NPD		
TR13455 0.1 ug/mL, 2 uL injection		
Run #	Retention Time, min	Peak Area
1	1.92	60143.00
2	1.92	58639.00
3	1.92	59189.00
4	1.92	60251.00
5	1.92	58005.00
Average	1.92	59245.40
Ave. Dev.	0.00	761.28
% RSD	0.05	1.28

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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