chromatec

Qualification of GC
Instrument qualification performed & documented in GLP format

Installation Qualification

Ensures that the instrument is installed according to the manufacturer requirements, and that all supporting documentation, spares, consumables and utilities are supplied or recommended. Also, the Installation Qualification (IQ) execution verifies that the equipment, and its ancillary systems or sub-systems have been installed in accordance with installation guides.

Operational Qualification

Ensures that the equipment will perform to its operational specification by testing and documenting key operational parameters relating to the individual instrument. All tests are based on Chromatec standard service procedures.

IQ – Installation Qualification

- Inventory of components and serial numbers;
- Installation verification;
- Initialization checkup.

Performance Verification

System checked for compliance with metrological parameters of detectors to manufacturer technical specifications. This involves detector baseline noise and drift, limit of detection and precision.

Complete documentation is provided including engineer training certificates, test reports and certification for all measuring test equipment.
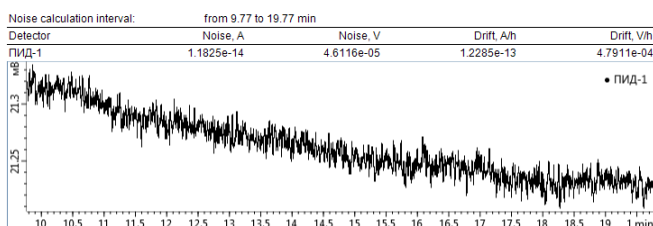
OQ – Operational Qualification GC Systems

- Software checkup;
- Checkup for leak proofness;
- Method control test;
- Temperature stability;
- Gas flow rate stability and accuracy.

PQ – Performance Qualification (FID, NPD, ECD, FPD, TCD)

- Detector noise and drift: the baseline drift value is considered as a maximal baseline drift level within 1 hour.

Noise calculation

Noise calculation interval:		from 9.77 to 19.77 min		
Detector	Noise, A	Noise, V	Drift, A/h	Drift, V/h
ПИД-1	1.1825e-14	4.6116e-05	1.2285e-13	4.7911e-04

- Minimum detection limit: to determine detection limit, the reference sample corresponding to checked detector is to be injected into GC five times or more.
- Injection precision: repeated injections of standard sample. Compare area, height count and retention time deviations.

Chromatogram	R. time, min	Area, mV*s	Height, mV	MDL, g/s
11/4/2014 3:32:29 PM №18	1,773	5 546,427	1 057,449	1.436e-12
11/4/2014 3:46:10 PM №19	1,775	5 535,827	1 057,535	1.439e-12
11/4/2014 3:58:56 PM №20	1,777	5 493,167	1 051,587	1.450e-12
11/4/2014 4:12:31 PM №21	1,778	5 491,397	1 049,054	1.451e-12
11/4/2014 4:24:25 PM №22	1,773	5 508,420	1 054,507	1.446e-12
11/4/2014 4:32:45 PM №23	1,780	5 481,125	1 045,925	1.453e-12
11/4/2014 4:42:18 PM №24	1,770	5 342,451	1 031,774	1.491e-12
11/4/2014 4:51:40 PM №25	1,775	5 516,302	1 051,873	1.444e-12
11/4/2014 5:02:11 PM №26	1,777	5 518,075	1 051,473	1.444e-12
11/4/2014 5:16:46 PM №27	1,783	5 343,876	1 029,228	1.491e-12
Average	1,776	5 477,707	1 048,041	1.454e-12
RSD, %	0,208	1,344	0,945	

- Detector response linearity: injections of increasing concentrations of samples in accordance with method of analysis. Compare linearity of area co

№ 139   Date 7/27/2015 11:28:34 AM   Sample Раствор А   Method -   Range ΔX=15.347 ΔY=69.88

Name:	МАУ
The number of degrees of freedom functions:	11
Coefficient of determination:	0.99955
Standard deviation, %:	51.255
Residual standart deviation:	0.03503
Relative standart deviation, %:	2.6422