



OPERATIONAL QUALIFICATION

The LC Services Ltd Operational Qualification Procedures have been designed in line with good laboratory practice (GLP) and good manufacturing practices (GMP), which require that all laboratory instrumentation shall be adequately inspected, cleaned and maintained. Instruments used for generation, measurement and evaluation of data shall be adequately tested, calibrated or standardised. LC Services Ltd protocol (available on request) will define the methods and documentation that will be used to evaluate the HPLC instrument or system for operation in accordance with the intended use. Successful completion of this protocol will verify that the HPLC instrument or system is operating to your acceptance limits.

OVERVIEW OF PROCEDURES

The OQ procedures use a combination of test functions and analytical methods (using certified samples and equipment) to evaluate and verify the instrument or system is operating according to acceptable limits.

PROCEDURES TO BE TAKEN PRIOR TO QUALIFICATION

All preventative maintenance/repairs must be completed and instrument test carried out prior to a qualification procedure being undertaken. In the event of any problems, consultation with LC Services Ltd Service Manager or Senior Engineer must be initiated. All standards and equipment used for qualification must be checked for compliance prior to qualification. Any certification for equipment/standards used are available on request.

PREPARATION OF CERTIFICATION

Once all equipment has undergone initial maintenance/repair etc. operational qualification can be carried out in accordance with this protocol. All raw data collected is obtained using

calibrated standards/equipment, which is traceable to nationally recognised standards. All chromatographic data is captured on the customer's system and folders are generated to store the data. The OQ is performed on our very own tailor made software and generates certificates on site and is electronically signed by the engineers' personal login.

FINAL CERTIFICATION

All criteria can be tailored to the customers individual specification and the final certification is backed up to the LC Services Ltd server.

PUMP FLOWRATE ACCURACY

- 0.5ml/min 1.0ml/min 2.0ml/min
- 10 readings at each
- RSD +/- 3%

PUMP GRADIENT PROFILE

- 5 steps at 20% A/B/C/D
- RSD +/- 3%

UV DETECTOR WAVELENGTH ACCURACY

- 241nm 287nm 361nm
- 9 readings at each
- Specification +/-2nm

AUTOSAMPLER REPEATABILITY

- 7 injections + 2 blank
- TLF +/-1% PLF +/-2%
- Carryover less than 0.1%

