

Validation Kit



A complete solution for Operational Qualification

The Validation Kit provides validation of the Clarity Chromatography Station. The chromatography system measures a set of signals from a precise peak generator. These signals are then evaluated using prepared validation methods. The resulting report can then be used to document the performance of the system.

Validation Kit includes:

- *Validator - precise peak generator device*
- *CD with files necessary for performing the Operational Qualification*
- *Clarity Validation Kit manual*
- *Cables*

Validation Kit

Complete solution for Operational Qualification (OQ)

The Validation Kit consists of a precise peak generator (Validator) and a set of methods for validating chromatography data stations. The kit is optimized for seamless Operational Qualification with Clarity software. The peak generator can also be ported to other software and hardware solutions.



Commonly, three levels of validation (qualification) are relevant for chromatography systems:

Installation Qualification (IQ): a procedure confirming that the data station was successfully installed and that the installation contains all the required files of the correct version. Installation qualification is an integral part of the Clarity Chromatography Station installation procedure.

Operational Qualification (OQ): a procedure confirming that the data station is performing according to the manufacturer's specification. The Clarity Validation kit serves this purpose. Using a precise peak generator, chromatographic data is acquired and analyzed with prepared procedures and the calculated results are compared to expected values.

Performance Qualification (PQ): a procedure confirming that the analytical system is fit for a given type of analysis. Usually, the overall system performance is tested by this procedure with respect to the requirements of the desired application. The Clarity offers many tools in the System Suitability Test (SST) module to efficiently evaluate the system performance.

Available Operation Qualification tests

- Retention Time Test for precision and accuracy
- Peak Height Test for voltage measurement precision and accuracy
- Area Test for determination of precision and accuracy
- Calibration and Calculations Test for ESTD and ISTD methods
- Acquisition Ranges Test for consistency of acquisition ranges

Specification

Part No.:	CVK
Warranty:	3 years
Related Products:	Clarity software (p/n C50) - required any A/D converter required - see www.dataapex.com for list of available converters SST Extension (p/n A22) - required

