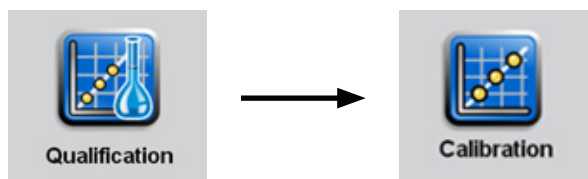




## QbD1200+ Analyzer Calibration

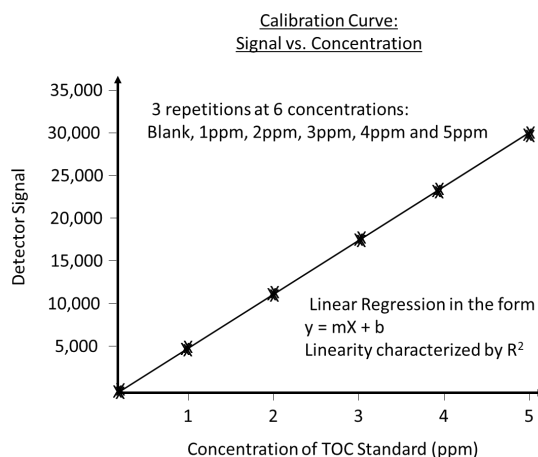
The calibration of a TOC Analyzer is a crucial part of ensuring a quality measurement. A commonly used definition of calibration is:

The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a traceable standard over an appropriate range of measurements.



### ***-US FDA Guidance for Industry, Q7A. Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients***

Calibration is typically conducted by taking multiple measurements at different concentrations of a known primary standard. International Conference on Harmonization (ICH) recommends using a minimum of 5 concentrations to demonstrate linearity across the instrument's calibrated range. The measurement signal can be plotted against concentration to produce a calibration curve. The figure below shows an example of a calibration curve generated on the QbD1200+ analyzer.



**The QbD1200+ analyzer calibration is designed to be convenient and easy to perform.**

#### Notes:

- Only a single 125 mL bottle of 5ppm KHP primary calibration standard is required during calibration.

6-point calibration (5, 4, 3, 2, and 1 ppm and blank).

The analyzer automatically dilutes this down (using One Reagent) to concentrations of 4 ppm, 3 ppm, 2 ppm, and 1 ppm TOC.

One Reagent without any added KHP standard is measured for the blank values.

- In regular measurement mode (not calibration), the QbD1200+ analyzer automatically checks unknown samples during an auto-range step. All samples >4 ppm TOC are automatically diluted down with the One Reagent.

Calibration performed up to 5 ppm will cover the full measurement range (0.4 ppb-100 ppm) because any samples that are >5 ppm are diluted down to <5 ppm.

- Calibration Pass criteria:

If the  $R^2$  of the calibration curve is  $\geq 0.99$ , then the calibration passes and can be accepted.

- Record keeping

Every calibration performed on the QbD1200+ analyzer is stored in the encrypted database.

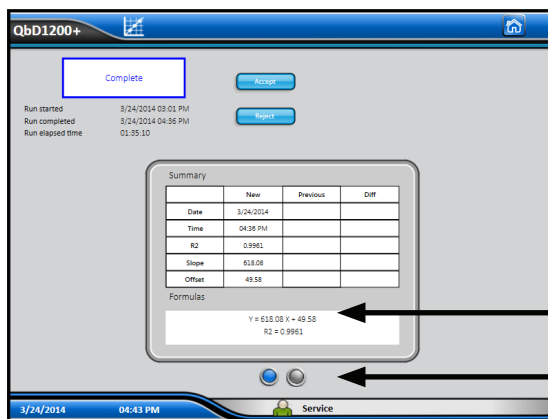
It is easy to create a report of all calibration records.

- Calibration time

Total calibration time for the QbD1200+ analyzer is approximately 90 minutes.

After a calibration, the results are clearly displayed in two formats: 1) table view; 2) graph view.

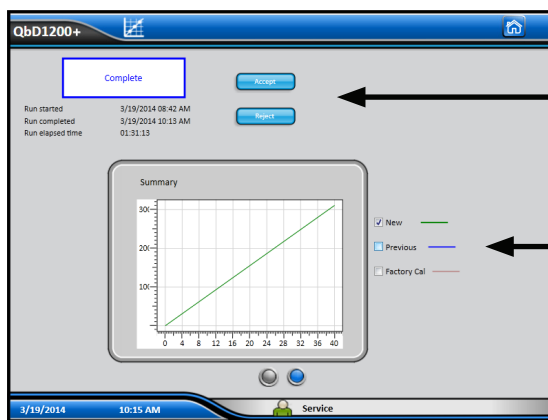
### Table view



Equation with  $R^2$

Swipe or touch circle to switch to Graph View

### Graph View



Option to choose Accept or Reject

Check box to display previous calibration curve