



Calibration

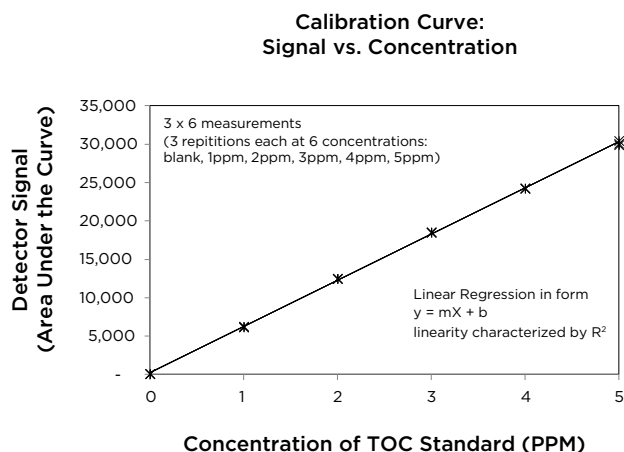


The calibration of a TOC Analyzer is a crucial part of ensuring a quality measurement. A commonly used definition of calibration is:

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. The 16th Edition of the Japanese Pharmacopeia (JP 16) and the International Conference on Harmonization (ICH) both recommend using a minimum of 5 concentrations to demonstrate linearity across the instrument's calibrated range. JP 16 further calls for KHP (potassium hydrogen phthalate) as the primary calibration standard. 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.



QbD1200 calibration is designed so that calibration is very convenient and easy to perform.

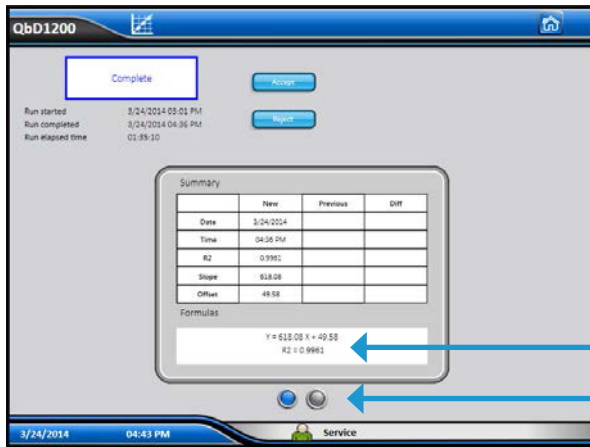
Notes

- Only a single 125mL bottle of 5ppm KHP primary calibration standard is required during calibration.
 - The analyzer automatically dilutes this down (using One Reagent) to concentrations of 4ppm, 3ppm, 2ppm, and 1ppm TOC.
 - One Reagent without any added KHP standard is measured for the blank values.
- In regular measurement mode (not calibration), the QbD1200 automatically checks unknown samples during an auto-range step. All samples >4ppm TOC are automatically diluted down with the One Reagent.
 - Calibration performed up to 5ppm will cover the full measurement range (1ppb-100ppm) because any samples that are > 5ppm are diluted down to <5ppm.

- Calibration Pass criteria
 - If the R^2 of the calibration curve is ≥ 0.99 , then the calibration passes and can be accepted.
- Record keeping
 - Every calibration performed on the QbD1200 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 is approximately 90 minutes.

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

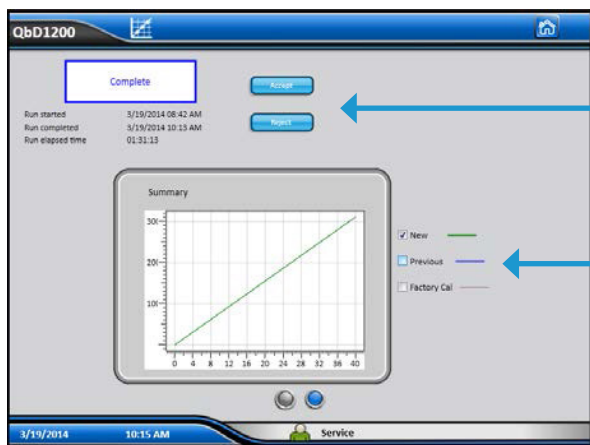
Table View



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