Thermo SCIENTIFIC

Tip Log # 94

Applications Tip of the Week

What is the difference between USP and EP pH Methods?

Question: What is the difference between USP <791> and EP 2.2.3. pH measurement methods? I was going over the data in the notebook, where an analyst wrote:

- Standardization was done using pH buffer 7.00 & 10.00 according to the USP <791> method.
- Standardization was done using pH buffer 4.00 & 10.00 according the EP 2.2.3 method.

Answer:
Both methods, the US Pharmacopoeia <791> and the European Pharmacopoeia 2.2.3., describe the potentiometric determination of the pH. These methods have many similarities in the requirements for pH electrode/meter systems so that results may be compared between laboratories.

There are the following main differences in these two methods:
1) In the pH calibration procedure.

- According to the EP 2.2.3. Potentiometric Determination of pH Method, the pH electrode/meter system is always calibrated with the pH 4 buffer and one other buffer solution of different pH.

- According to USP <791>pH Method, you do not have to start calibration with the pH 4 buffer – it says: "To standardize the pH meter, select two Buffer Solutions for Standardization whose difference in pH does not exceed 4 units and such that the expected pH of the material under test falls between them."

This can explain why the analyst used the pH 4 and 10 buffers for the EP calibration and pH 7 and 10 buffers for the USP <791> calibration.

2) There is a difference in the acceptable accuracy for the pH measurement.

- When reading back standards to verify the calibration, the acceptable accuracy for the USP <791> method should be within +/- 0.02 pH units of the expected value for that temperature.
- According to the EP 2.2.3. method, the pH of the buffer used to verify calibration must not differ by more than 0.05 pH units from the value corresponding to this solution.

3) The temperature measurement requirements are slightly different too.

- The EP Method says that "all measurements are made at the same temperature (20-25ºC)".
- The USP <791> Method recommends measurement at 25+/-2ºC.