Measuring pH of Ophthalmic Solutions

Description

Ophthalmic solutions are sterile solutions designed specifically for use as eye drops. Some eye drops are simply designed to provide lubrication for the short-term relief of dry eyes; others are compounded with medications such as antimicrobials or steroids to treat ocular diseases. Ophthalmic solutions are the most popular means to apply medication to the eyes due to their ease of administration and relative low cost as compared to alternative methods.

Product formulation is a critical step in the development of an ophthalmic solution. A variety of parameters must be strictly controlled to ensure a safe and effective product. These parameters include sterility, impurity content, osmotic balance, and pH. The solubility and stability of the active components of ophthalmic solutions depend on the pH. The pH of the solution can also impact the comfort and safety of the product. Normal tears have a pH of approximately 7.2 to 7.4; introduction of an ophthalmic solution outside of this range will cause discomfort and irritation. Eye irritation typically causes additional tear production that may flush the ophthalmic solution from the eye, thus reducing the amount of active medication actually delivered to the eye.

Ideally, ophthalmic solutions would have a pH mimicking natural tears, but a compromise must be made to account for drug stability and solubility. Typically, these solutions are weakly buffered at the ideal pH of the drug, and are then neutralized by the natural tears of the human body. However, minor contaminants in the production process can easily overcome the buffering capacity of the ophthalmic solution; this means that the pH of ophthalmic solutions is prone to drastic shifts. Tight control over the pH is necessary to ensure product effectiveness.

Application

A manufacturer of eye drops contacted Hanna Instruments with interest in a benchtop pH meter for their quality control laboratory. It was critical that the benchtop instrument offered features that are compatible with the pH measurement method specified by the United States Pharmacopeial Convention (USP). Hanna Instruments offered the HI5221 Research Grade pH/ORP Meter with CAL Check™. The HI5221 offers calibration up to five points with automatic buffer recognition with either the Hanna standard buffer set or NIST buffer set. This feature was appreciated, as the customer was using the NIST buffer set (pH 1.68, 4.01, 6.86, 9.23, and 12.45) and was required to calibrate with NIST-traceable buffers in accordance with the USP method. The inclusion of an extensive GLP features allowed the customer to easily recall detailed calibration information, as well as verify the frequency and accuracy of pH electrode calibrations. The customer was also pleased that GLP data was included with logged data points for tracking purposes. To accompany the HI5221, the Hanna Instruments sales representative recommended the HI1083B refillable combination pH electrode with micro bulb. The junction for the micro bulb electrode is located just three millimeters above the bottom of the electrode, making it ideal for measurement in small sample sizes. Since the finished ophthalmic solutions tend to be expensive and limited in quantity, the low sample volume required for measurement provided value to the customer. The HI5221 and HI1083B provided a complete solution for their pH quality control program.