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Diluent pH specification setting for freeze-dried vaccines

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Many vaccines on the market and in development use freeze-drying method to conserve the product potency and extend shelf-life. These vaccines need to be reconstituted with diluent before application in patients. Diluent used for freeze-dried vaccines is often made of water for injection (WFI), saline, or buffered saline. When using WFI or un-buffered saline as diluent, care has to be taken when selecting the tests and choosing the acceptance criteria. This presentation showcases one example where the diluent pH measurement exceeded the specified range during long-term storage, for a freeze-dried product in development., If the situation was not rectified, the risk could be a possible delay of a clinical trial. Towards solving this problem, various aspects were investigated, including container and enclosure system, pH probe and meter, sample preparation method. The root cause was determined to be leaching from the borosilicate glass vial. In un-buffered media with pH under 7, sodium ions, among other leachables, would exchange with hydrogen ions in the media leading to increase in pH. Reported levels of the leachables from similar glass were reviewed and safety was not a concern. In addition, the investigation included a study demonstrating that the pH of the reconstituted product was not impacted by diluent with a wide range of pH, for the product itself contained phosphate buffer. Based on this study, the acceptable pH range was widened for the stability programs. For future diluent batches, the plan was to eliminate the pH test, for the pH of the vaccine was determined by the buffer in the freeze-dried product, not by diluent.

Biography

Hong SUN completed her B.S. from Peking University, Ph.D from University of California, Los Angeles, and postdoctoral study from University of Toronto. She is a senior development scientist at Sanofi Pasteur in Toronto and has eight years of experience in viral vaccine and recombinant protein vaccine development.

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