SiO2 Medical Products™
SCIENCE INSIDE™

pH Shift of WFI Stored in Glass Vials and Cyclic Olefin Polymer (COP) Vials with Trilayer Oxygen Barrier Coated Vials

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Keywords: Coating, Vials, Water for Injection, glass, cyclic olefin polymer, COP

Objective

The objective of this study is to determine how well SiO_2 Medical Product's (SMP) coated COP vials maintain water for injection (WFI) relative to standard borosilicate glass. A pH shift in WFI stored in glass containers has been observed. This study will determine the effect of SMP's coated and uncoated vials on the pH of WFI stored in them.

Introduction

It is well known that type I borosilicate glass is not an ideal material for the long term storage of small volumes of WFI. Over time, ion exchange of glass inorganic ions particularly Na^+ for H^+, increases the OH^- concentration leading to an increase in pH. WFI is unbuffered, therefore the pH is very sensitive to changes in the relative concentration of OH^-. If the pH changes during storage it is indicative of leaching of compounds from the glass walls which could cause delamination and failure to comply with pharmacopeial specifications such as conductivity, etc.

This study will evaluate WFI stored in coated COP versus standard borosilicate glass at room temperature, 40°C, and 60°C.

Glass vials and coated COP vials will be filled with the same lot of WFI whose initial pH has been measured. The filled containers will be put on stability at 25°, 40°, and 60°C over a specified length of time. At various time points several of each type of container will be pulled and the pH of the solution measured.

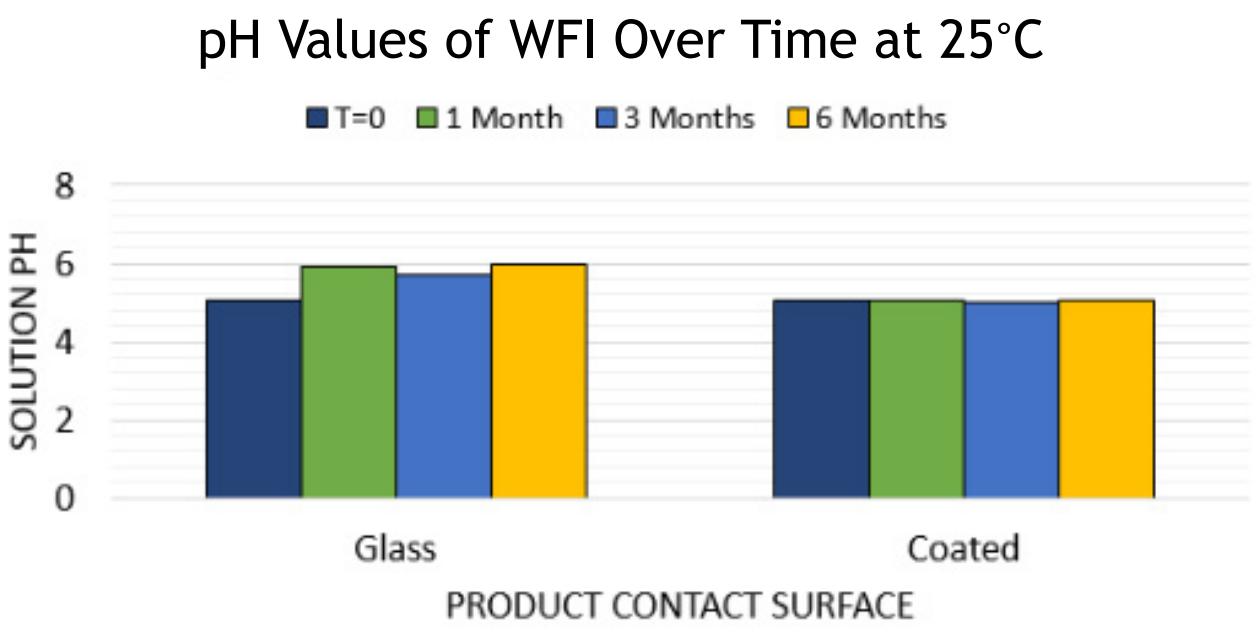
Test Articles

All samples will be sterilized. Glass vials will be rinsed with WFI and depyrogenated by heating to 250°C for 2 hours to expose the glass to conditions that it would experience during pharmaceutical processing before sterile filling.

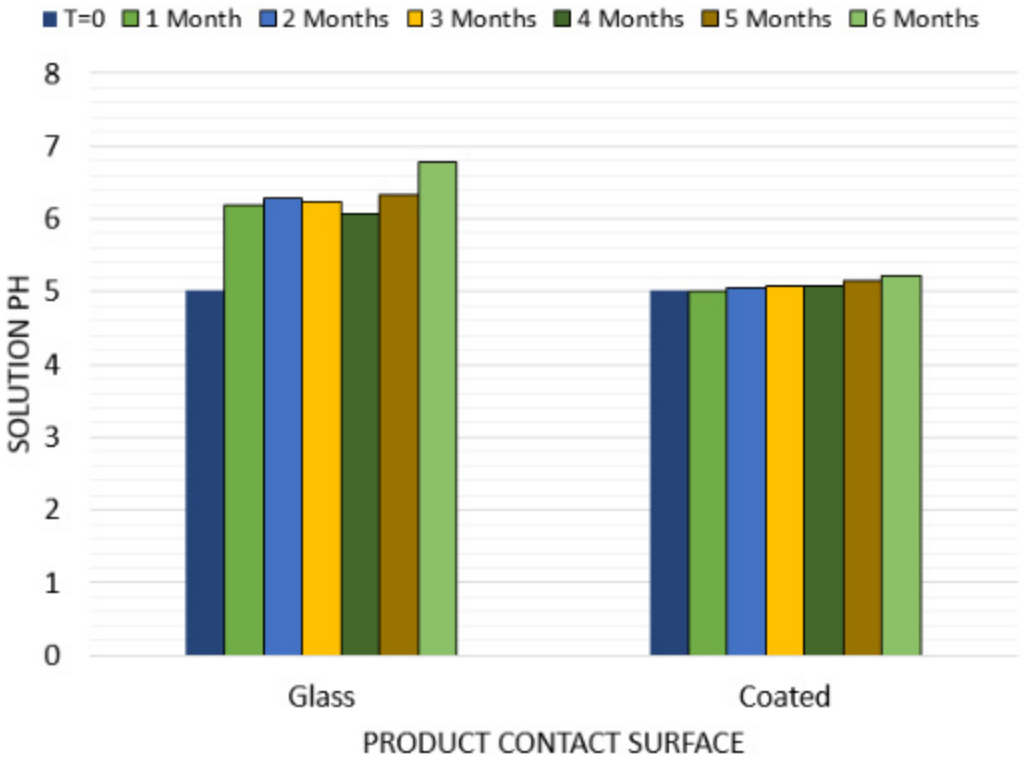
Filling and pH Measurement

Vials will be filled with 5 mL of WFI which has been purchased and filling will take place in a laminar flow hood using aseptic technique. Saturated KCl solution will be added to the samples just prior to measuring the pH at the rate of 0.3 mL per 100 mL of solution to provide enough ionic strength to the solution to help stabilize the readings.

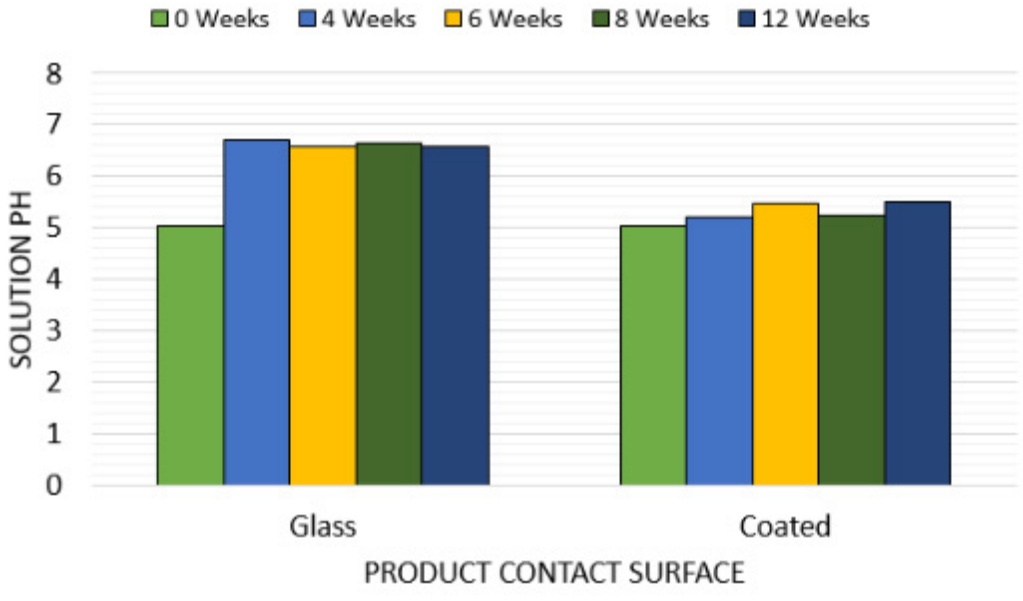
Results



pH Values of WFI Over Time at 40°C



pH Values of WFI Over Time at 60°C



Conclusions

As expected, pH values of WFI did not change significantly when packaged in barrier coated COP. There was up to 2 pH units change in WFI packaged in glass. This is indicative of compounds leaching from glass into the WFI. This could lead to delamination and could cause drug products to go out of compliance with pharmacopeial monographs or product specifications. By using COP vials the leaching of packaging components and delamination of glass flakes into the drug product can be mitigated.