

PennTech Newsletter

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Quote of the Week

*"People get caught up in wonderful, eye-catching pitches, but they don't do enough to close the deal. It's no good if you don't make the sale. Even if your foot is in the door or you bring someone into a conference room, you don't win the deal unless you actually get them to sign on the dotted line"....
Donald Trump*

Next Weeks Topic

* Understanding Passivation *

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Validation of Vials After Washing...

There are various different tests that can be performed to validate vials after vial washing. Following, we'll discuss three:

Particulate Evaluation Test

The purpose of this test is to assure that the vial washer reduces the particulate levels of the vials during the wash process. Challenge vials and positive controls are to be spiked using certified particle size standards. The particle standards used will consist of polystyrene latex beads of approximately 50 micron size suspended in an aqueous solution. Each vial is spiked with a polystyrene latex bead aqueous solution - enough to obtain approximately 2000 particles per vial. The solution must cover the bottom and the sides of the vials. The vials must then air dry under a laminar flow hood or warm room for approximately 48 hours. The vials are then washed in the vial washer. Once washed, the vials are filled and rinsed with purified water. At this point a particulate analysis (using a particulate counter) is performed testing for particulates 10-25µm. Vials must show a particulate reduction of at least (>) 1 log reduction over the unwashed vials average particulate levels for the 10µm particle size.

Riboflavin Challenge Test

A 0.02% riboflavin solution is prepared by adding 0.2g of riboflavin per 1000ml of purified water. The riboflavin solution is applied to the internal surfaces of the vials. Riboflavin is visible as small yellow/green droplets when applied. The vials are air dried under a laminar flow hood for approximately 48 hours. The vials are then washed in the vial washer. After the cleaning is complete, all wetted surfaces are inspected for remaining riboflavin using a UV lamp at either 365 or 254nm wavelength to fluoresce the riboflavin for detection. The test is failed if any trace of riboflavin is found. All test articles must show 100% clearance of the surface coating of riboflavin.



Sulfur Treatment Test

The purpose of this test is to confirm the absence of residual sulfur remaining from the sulfur treatment on the washed vials. To each vial, 10 drops of distilled water and 1 drop hydrochloric acid is added. Each vial is manually rotated to assure a complete coating on the glass. One drop of barium chloride T.S. (12%) is added to each vial. The appearance of white turbidity in the unwashed vial indicates barium sulfate crystals, confirming the presence of sulfur. The vials are then washed in the vial washer. The vials are then inspected for the absence of white turbidity. The absence of residual sulfur indicates that the washing process removed the residual sulfur from all test vials.