

January 2010 What's an "Equivalent" Swab?

In my training seminars (and in the recent webinar on swab sampling), I always caution against specifying a certain swab or an "equivalent". My concern is with the "or equivalent" part. How is "equivalency" defined or determined? It is not prudent to use a certain swab from one manufacturer, and ask another manufacturer for its equivalent, thinking that it will be an exact match. That second swab manufacturer may define "equivalent" as "for the same application". For example, "this swab is equivalent because it is for the same purpose (such as for TOC swabbing)". In such a case, are the size, shape and composition of the swab head (as well as the length and flexibility of the swab handle) the same such that performance and recoveries would be the same? For clarification, I'm not saying you can't switch to a different swab. You can switch to a different swab, but then recovery studies should be repeated for that new swab and operator training should be required.

Ordinarily, I would not encourage a situation where you specify that either "Swab A" or "Swab B" could be used for the same residue. Certainly you can have one swab for microbial sampling and one swab for chemical residues. You might also need to have one swab for sampling with HPLC analysis and a different swab for sampling with TOC analysis. However, it is better for training purposes to only have one swab for chemical residues. Among other things, this prevents mix-ups in terms of the wrong swab being used (the "TOC swab" being used accidentally when you should be using the "HPLC swab").

On the issue of "equivalency", my eyes were opened even further based on some recent data obtained from a swab manufacturer. What I was really interested in was how much liquid was held by different swabs in a typical procedure where the swab is dipped in water and then the excess liquid "expressed" out by pushing it against the side of the vial. I was trying to get information that would help me understand the variability of how much liquid would be left on a surface after swabbing. The data that I saw surprised me in a different way.

What the company provided me was two sets of data using different test conditions. One condition involved dipping the swab in water for 60 seconds and then holding it out of the water for 60 seconds to allow any excess water to drip off. The second condition involved doing the same thing, except then expressing excess liquid by pressing the swab against the side of the vial.

For perspective, these were swabs which are typically used for cleaning validation, and included knit polyester and non-woven polyester, different sized swab heads, and different laundering practices. The latter refers to the fact that many swabs used for TOC analysis involve an additional laundering step to lower the "background" TOC. Also, there were no cellulose or polyester/cellulose blends evaluated.

Here, in a nutshell, is what the data showed. First, for most of the six swab types, there was very little difference between the amounts held by the swab with a 60-second drain time as compared to the situation where the swab head was expressed against the vial sidewall. This was not expected (at least by me). To put this in perspective, the data might be different if the water soak time was an hour before the drain step (but this is just my speculation). In other words, the rate of picking up water was not considered in this evaluation.

What was even more unexpected was the difference between what were essentially the same swabs except for

the laundering step. I had expected that the amounts absorbed would increase with laundering. This was based on what I knew about cotton fabrics, that you could launder cotton to remove the natural waxes so as to make it absorb better. Data trumps theory, and the data indicated that these laundered swabs absorbed only 20% of the amount absorbed by the similar unlaundered swabs. For clarification, that is not 20% less than the amount absorbed by the unlaundered swabs; it is 20% of the amount absorbed by the unlaundered swab. This held true for two sets of swabs, one set with a relatively large swab head and one set with a relatively small swab head.

How could this be? My speculation (based on my involvement in the textile industry a long time ago) was that the unlaundered polyester had surfactants on it which were removed by the laundering process. The surfactants were part of the polyester manufacturing process (perhaps during knitting). For “TOC swabs”, the polyester is laundered to reduce the TOC value due to extractables. Was it possible that the presence of those surfactants allowed for a greater wetting, and hence greater absorbency, for the unlaundered swabs? When I suggested that explanation to the swab manufacturer, they seemed to agree that it was a reasonable explanation.

Let me also clarify that some people refer to mechanisms for holding water differently. They use absorbance for cellulosics (where the liquid is held inside the fiber) and adsorbance for polyester (where the liquid is held between the fiber bundles). For simplicity, I am referring to what is picked up by either mechanism as “absorbance.”

The limited range of these swabs should be considered when evaluating these findings. However, the surprising results (or at least what I considered surprising results) of this limited range suggest that care in specifying materials of construction of the swab is critical. And even more care needs to be used in selecting an “equivalent” swab. This data is also only with water, and data for other solvents may be different. However, what this suggests is the need to carefully qualify swabs, as well as the need for swab manufacturers to consider adding a specification relating to “absorbance” for swabs. It also suggests that the practice of pressing the swab head against the vial to express excess liquid may not be significant.

This involves experiments that are fairly easy to perform. If anyone want to try this with their swabs (measuring absorbance under different conditions), and then wants to share the data, please send the information to me. I will try to summarize the data and share it for all to review.

Let me clarify that the point of this Cleaning Memo is not to specify certain practices. Rather it is to remind us all that for a very simple procedure, which some people like to call a “precise” sampling procedure, perhaps we still have more to learn.