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Selecting the Swab Sampling Area

This Cleaning Memo addresses the question of the specific surface area to swab in a cleaning validation protocol. For clarification, this will address the size of swab area, not the location of the swab area. Most companies will swab areas of 25 cm² (4 square inches) to 100 cm² (16 square inches), although I have seen swab areas as large as 400 cm².

There are no regulatory guidelines for selecting the size of the area to be sampled. Note, however, that there has been at least one FDA 483 citation for using too small an area for sampling environmental surfaces for penicillin. It should be noted that this concern was specific to this situation, in which it was probably believed that swabbing a smaller area was less likely to detect penicillin contamination on environmental surfaces.

What are the advantages and disadvantages of different swab areas for swabbing? For simplicity, we will consider sampled areas of 25 cm² as a small area and 100 cm² as a larger area. In each point discussed below, it will be considered on an “other things being equal” basis.

One advantage of swabbing a larger area is that the residue limit in the analytical sample will be higher. This means that the limit of detection or limit of quantitation of the analytical limit could be higher. For example, if I swab 100 cm² and then desorb it into 20 mL of solvent, the residue limit in the analytical sample will be four times larger than the residue limit if only 25 cm² were sampled and the swab desorbed into 20 mL of solvent. Note that while the limit in the analytical sample is higher with the larger surface area, there is no difference in terms of the risk of passing or failing (because the amount of residue potentially swabbed from the surface will be four times as great with the larger surface area).

One advantage of swabbing a smaller area is that I am more likely to get a higher recovery. As a general principle, the larger the surface area the lower the recovery. This may be due to the fact that when I use a wet swab (as is usually the case), I am going to leave a finite amount of liquid on the swabbed surface. The larger the area swabbed, the more liquid will be left behind. It should be noted that the difference may be small in comparison to the overall recovery. One way to minimize this effect is to use two swabs on the same surface area, with the second swab being dry.

Another factor in the use of a larger area is that there may be less variability in the actual area sampled. If I am off by a length of 0.5 cm in each direction for my swabbing, then the variability of area coverage may be as much as ± 10% for a swab area of 100 cm². If I am off by the same 0.5 cm in each direction for a swab area of 25 cm², then the variability of area coverage may be as much as ± 20%. This effect can be negated if I were to use a template for controlling the sampled area (instead of using the “eyeball” method).

A final consideration is that by selecting the smaller surface area (25 cm²), the more likely it is that all sampling locations will have that area available. With a larger surface area of 100 cm², the more likely it will be that there will be certain locations where I can't sample a full 100 cm² (for example, perhaps only 80 cm² is available for swabbing). In addition, the smaller the swabbed area the more likely it will be that I will be able to sample a location that would be square (for example, 10 cm X 10 cm as opposed to 5 cm X 20 cm). This issue is situational, and may or may not be significant. Note also that I am not addressing the issue of how to

handle recovery if a different swabbing shape is used. I am just stating that the situation of having to use a different shape (other than square) is more likely to occur the larger the swabbed area.

These are some of the considerations in selecting the size of the swabbed area in a validation protocol. Needless to say, for training and consistency reasons, one should generally select one specific size for swabbing in protocols and in recovery studies.

The purpose of this Cleaning Memo is not to proscribe or prescribe a certain size for swabbing purposes. The purpose is cover various features of swab sampling that are impacted by the size selected for swabbing.