

CVB Inspection and Compliance Policy Concerning Purity Test Expectations for a Serial in Multiple Containers Sizes

Background

Title 9 CFR 113.26(a) describes the requirements for the detection of viable bacteria and fungi except in live vaccine. Test vessels shall be used for each of the media selected for the detection of bacteria and fungi. Veterinary Biologics can be presented as one serial with multiple container sizes. The following policy describes the expectations of representative samples used for the test.

Inspection and Compliance Policy

The standard operating procedure for *Product Sampling*, ICSOP0022, indicates that sampling should include all container sizes of the same serial in representative proportions.

The proportions in this case represent the percentage of container sizes for the serial. For example:

- A serial inventory that consists of 70% of volume A and 30% of volume B should be tested using 70% of representative samples from volume A for each of the media selected, and 30% of representative samples from volume B for each of the media selected for the test. For a standard test, this would be 7 vials of Volume A and 3 Vials of Volume B for each media type required.
- Firms have the option to test 100% of volume A and 100% of volume B for each of the media selected for the test.
- Instances when the percentage of container size is less than 1% should include at least 1 vessel for each of the media selected for the test.
- Veterinary biologics firms also have the option to exempt the test specifics in the outline of production on file at the CVB.

Regulatory Actions

Deviations from the test procedures may be violations of the sampling procedures in accordance with 9 CFR 113.3 and as a result, violations to the test procedures in accordance with 9 CFR 113.26. Serials released to the market and found to be not tested appropriately are subject to an APHIS Mandated Stop Distribution and Sale. Contact a Section Leader or the Investigation Manager at the office for direction and action. Serials found on test during inspection must be tested appropriately prior to consideration for marketing release. A Hold Release may be initiated if needed.