TECHNICAL TIP

WHAT IS BIOBURDEN RECOVERY EFFICIENCY AND HOW TO APPROACH LOWER THAN DESIRED RECOVERY RESULTS

What is Recovery Efficiency (RE)?

Recovery Efficiency (RE) is an important part of the validation of the bioburden test method. It is intended to provide an assessment of the efficiency of the extraction technique to remove viable microorganisms from a product. This efficiency is used to provide a numerical value called the Correction Factor, which is applied to the product bioburden.

There are two acceptable methods for the measurement of the recovery efficiency according to ISO 11737-1: Inoculated recovery and repetitive extraction, sometimes referred to as exhaustive recovery.

NOTE: Prior to initiation of RE, it may be necessary to perform preliminary experiments to determine the technique to be used. Rationale for choosing a particular validation technique should be documented.

Inoculated Method Bioburden Recovery Efficiency

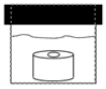
For the inoculated method, product typically has low bioburden or is pre-sterilized to remove the impact of other competing microorganisms from obtaining an accurate count of the inoculated organism. Typically, a spore-forming microorganism, such as *Bacillus atrophaeus*, is spiked directly onto the device in a liquid suspension and allowed to dry, to simulate product bioburden. The recovery efficiency is calculated by comparing the colony count of the target microorganism recovered to the positive control. This is the preferred method as there is a known starting population. It is typically used for products with low levels of native bioburden where repetitive extraction could yield no measurable counts.

Example:

Inoculate the product with approximately 100 Bacillus spores.

Allow to dry.

Place the product in the jar with sterile extraction fluid sonicate and shake the jar.



Assay the extraction fluids for colony forming units (CFUs) and compare the count obtained from the product to that of the inoculum population.

Inoculum population = 125

CFU recovered in one rinse of the product = 105

Single-rinse recovery efficiency = 105/125 = 84%

Correction factor = 1/0.84 = 1.2

If the CFU count on the filter is 80,

Bioburden result: 80 x 1.2 = 96 CFU

Repetitive Method Bioburden Recovery Efficiency

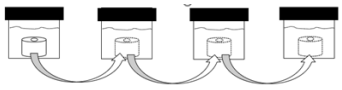
Repetitive (exhaustive) recovery is an additional option for determination of recovery efficiency. In this method, product samples are repetitively rinsed up to five times. After each rinse, a measure of viable bioburden extracted is made. Efficiency is calculated by comparing the total number of colonies recovered from all rinses to the first rinse. This approach is not suitable for certain product types that dissolve or are suspended such as powders or gels.

Example:

Place product in a jar with sterile extraction fluid, sonicate and shake the jar.

Assay the extraction fluid for CFU.

Perform three more extractions and assays.



FOR MORE INFORMATION

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Compare counts from the 1st rinse to the total four rinses value.

First rinse = 130

Second rinse = 35

Third rinse = 10

Fourth rinse = 1

Total rinse value = 176

First rinse recovery efficiency = 130/176 = 74%

Correction factor = 1/0.74 = 1.4

If CFU count on the filter is 80,

Bioburden result: 80 x 1.4 = 112 CFU

What is a Correction Factor (CF)?

The CF is a multiplier derived from the validated test method and applied to the viable count recovered in a bioburden test. This is referred to as a bioburden estimation and is used to account for the incomplete removal of native bioburden from the product. Per ISO 11737-1, C.1.4.1, bioburden that is adjusted for recovery is understood to more accurately represent the bioburden of the product. (Reference Bioburden Routine Testing TechTip)

The CF derived from a RE test is applied to future bioburden testing which may include aerobe, spore-former, fungi, anaerobe. The incubation and/or treatment (i.e. heat shock) of these various analysis may differ as specified by laboratory SOP.

Causes of "Low Recovery"

A "low" RE may indicate that either the applied method of extraction is not as efficient as desired, the nature of the product is not conducive to recovery, or there are interfering substances with the recovery of microorganisms. Product interference may be physical, or chemical. Chemical interference should be investigated and neutralized.

What Can Affect Recovery Efficiency?

- Product size, complexity, configuration
- Material
- Absorbency/porosity
- Adhesives or bonding agents
- Antimicrobial or inhibitory properties/agents
- Residual from cleaning process agents applied during manufacturing
- Materials that may break down or slough off when agitated in aqueous solution

What Options Are Available for Low Recovery?

- Reassess product for method improvements
  - Larger test container
  - Change in test rinsate (Buffered Water with Tween 80, Fluid D, etc.)
  - Longer extraction time
  - Added agitation steps
  - More vigorous agitation steps (shaking, stomaching, etc.)
  - Change in plating method (pour plate, membrane filtration, etc.)
- Perform an alternative RE method (inoculated/exhaustive)

NOTE: As part of the method validation, screening for adverse substances should be considered. Unlike the bioburden recovery efficiency, which is determining the removal of microorganisms from the product, this test looks at the method regarding the impact on microorganisms when they have been removed from the product—i.e. if substances present after the extraction process impact the quantity of microorganisms recovered (reference Screening for Adverse/Inhibitory Substances TechTip).

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