Container Closure Integrity Testing (CCIT)

Features

Pharmaceutical and some food products are expected to be free from microbial contamination and safe to use right from production throughout their shelf-life, but different products and container types necessitate different testing methods according to their content, material of packaging, design and regulatory requirements.

Container Closure Integrity Testing (CCIT) (USP <1207>), commonly referred to as leak detection, is a non-destructive packaging inspection system to maintain an aseptic barrier against potential contaminants. Is a deterministic testing procedure, so it is less subject to error, is repeatable and gives quantitative and predictable results.

Why Container Closure Testing is important:

CCIT detects defects that demonstrate breach of the container and/or closure system.

Patient and consumer health and safety is the principal reason why testing methods are put into place. Product sterility and consumer safety begins at the product development phase by evaluating the suitability of primary packaging in its ability to offer a sterile barrier thanks to its container closure system which should not result in contamination or leaks of the drug or product.

The United States Pharmacopeia (USP) and Food and Drug Administration (FDA) impose strict requirements for Container Closure Integrity Testing (CCIT).

As per the 21 Code of Federal Regulations (CFR) part 211.94, container closure systems must provide adequate protection against anticipated external factors in storage and use, that can cause deterioration or contamination of the drug product. It also establishes the standards or specifications and methods of testing in the validation procedures.

The leak detection guidelines establish that container security testing methods should use analytical detection techniques appropriate to the method and compatible with the specific product being tested. Validation of methods should be specific to the product container and closure system or product type.

How the CCIT method works:

- Common CCIT methods:
- Vacuum Decay Method
- Pressure Decay Method
- Lid Deflection
- Force Decay
- Headspace Gas Analysis (HGA)

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