PRODUCT NOTE

CCI Test Vessel

LIGHTHOUSE
The Science of Pharmaceutical Manufacturing

The CCI Test Vessel provides a simple means of preparing samples for container closure integrity testing (CCIT) using the highly-sensitive and non-destructive laser-based headspace analysis technology.
When combined with a LIGHTHOUSE FMS Headspace Gas Analyzer, the CCI Test Vessel offers a robust solution for container integrity tests on a wide range of container types and packaging conditions.

CCI TEST METHOD

The CCI test method utilizes laser-based analysis to measure changes in the headspace gas composition or pressure in a container that result from gas ingress through a leak.
The CCI Test Vessel creates an environment that accelerates this gas ingress through an open defect. Samples are placed inside the vessel and exposed to a tracer gas before the headspace measurement is performed. This approach is similar to a dye ingress test but takes advantage of the more sensitive gas ingress and employs a non-destructive and deterministic analytical measurement as the leak test.

VESSEL SPECIFICATIONS

- Electropolished stainless steel exterior and interior
- All stainless steel components
- Analog vacuum/pressure gauge
- Removeable perforated stainless steel sample shelf
- Sample capacity: approx. (100) 2R vials, (35) 30R vials or (20) 50R vials on sample shelf
- Dimensions: 28 x 36 cm (W x H)
- Pressure rating: 132 psig / 9.1 barg
- CE and ASME certified

CCI TEST VESSEL CASE STUDY

A method development study was performed to demonstrate an appropriate CCIT method for a 15R vial packaged with an air headspace. Samples would be exposed to carbon dioxide in the CCI Test Vessel (Figure 1a) and then inspected on the LIGHTHOUSE FMS-Carbon Dioxide Headspace Analyzer. Any samples with a defect would exhibit an increased level of carbon dioxide in the headspace.

Positive control vials were created using 5µm laser-drilled glass defects and sealed with one atmosphere of air in the headspace. The positive controls were tested to ensure low initial levels of carbon dioxide before being placed into the CCI Test Vessel for conditioning. The vessel was evacuated for 60 seconds using a vacuum pump then filled with carbon dioxide to a pressure of 20 psi (1.4 bar) above atmospheric. After 30 minutes the vials were removed from the vessel.

A second headspace analysis was performed to determine if the carbon dioxide had increased. All positive controls experienced a substantial increase in carbon dioxide in excess of 450 torr (600 mbar) and were easily identified as leaking containers using the FMS-Carbon Dioxide system (Figure 1b).

METHOD DEVELOPMENT

The gas ingress CCIT method can be designed according to the critical leak size for a specific product configuration. Validated mathematical models like those shown here (Figure 2) define the rate of gas ingress based on container size, headspace conditions, and leak diameter, providing the flexibility to define the appropriate CCI test protocol for each product and package.

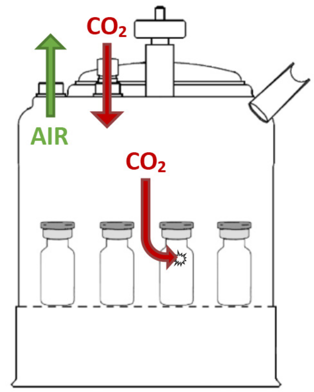

Figure 1a

Figure 1. CCI Test Vessel Demonstration. Samples are exposed to carbon dioxide in the CCI Test Vessel, prior to headspace analysis. Defective vials will reveal elevated headspace carbon dioxide levels (1a). All positive controls reveal elevated carbon dioxide levels after being exposed to carbon dioxide in the CCI Test Vessel (1b).

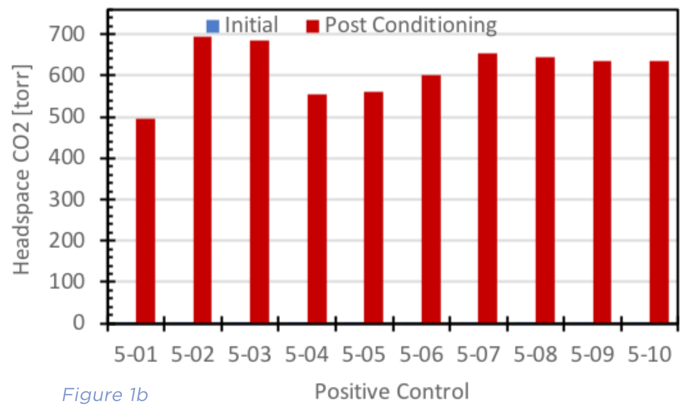

Figure 1b

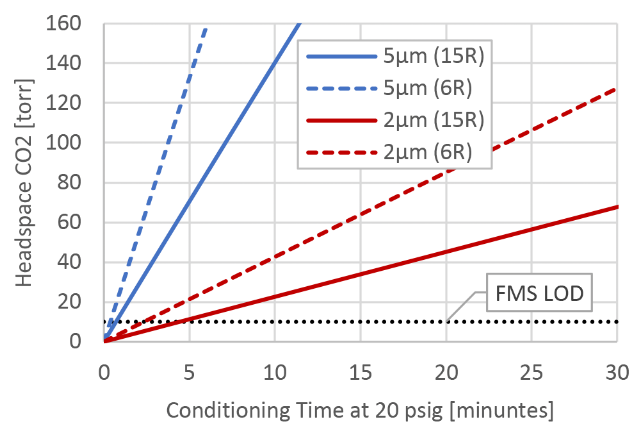

Figure 2. Gas Ingress Model. Validated mathematical models can be used to define the rate of gas ingress, for a specific product configuration and critical leak size.

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