Non-Destructive / Non-Intrusive IV Bag Headspace Oxygen Measurement

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Summary

The study demonstrates the applicability, to use the Gasporox GPX1500 Film Pharma instrument as a non-destructive method to test IV-bags. This fast and easy to use at line /lab measurement instrument generates the benefits of not scrapping products and simplifies the testing.

Introduction

Residual Headspace Oxygen is an important quality attribute in the parenteral packaging process. It is used to successfully verify the nitrogen purge process or as a leak test method, to verify the container closure integrity, develop container closure systems, do oxygen diffusion studies, confirm the effectiveness of an oxygen absorber or test the product over the shelf life.

Oxygen sensitive large volume parenterals (LVP) are frequent packed in IV bags. To guarantee and prolong the shelf life, a secondary packaging is required. This typically includes an oxygen absorber. This critical attribute of the absence of oxygen is verified during the production process. Today's typically used technologies are destructive and/or intrusive. Sample preparation is required to perform the measurement. All these methods do not allow the use of the tested containers for the market. It needs to be rejected and is lost for the use in the market.

The developed and patented technology used with the GASPOROX GPX1500 Film Pharma allows an easy and fast non-destructive testing of IV bags. It can measure small bubbles of headspace, and it is independent on the liquid type and colour. It is demonstrated to measure the primary bag, the secondary bag and the primary bag without unpacking from the secondary bag.

Study

The goal of the study is the comparison of the method with the actual reference method in a lab and the applicability of the instrument use in the production with operators.

The results presented are for measuring mono bags of an oxygen sensitive drug product. The bags are packed in a secondary bag.

Reference method and correlation

The destructive instrument requires to stick a rubber pad on the film. The needle of the instrument is piercing the film of the bag though the rubber pad. When starting the process, the gas from the headspace bubble is pulled in the instrument to the sensor element. An incorrectly placed rubber pad can generate bypassed air pulled in the instrument, which generates a wrong result by measuring not only the gas from the headspace.
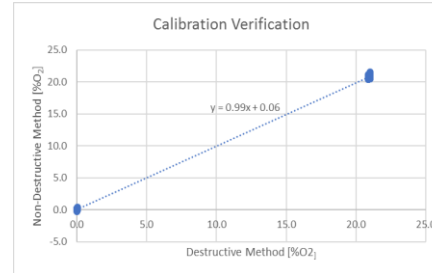
The correlation of the instruments was verified using 10 different bags. 5 are filled with air and 5 purged with Nitrogen.

GPX1500 Film Pharma

The instrument uses a laser which is shining in the small headspace bubble. The Oxygen molecules are absorbing the laser light and the Oxygen concentration is calculated. To assure that the headspace gas is in the measurement zone, a portion of the film is lifted. There is no need of adding something to the IV bag or doing a preparation of the bag. The only thing to be assured is that the position of measuring is not on printed area, which risks blocking the laser light from shining to the headspace.

Results

A total of 7 bags was used for the study. Each bag was measured 10 times with the Non-destructive method and after with the destructive method. The study contains a total of 210 measurements. As the measurement resolution was set to 0.1%, many measurements in the graphs are overlaying and shown only as one dot.
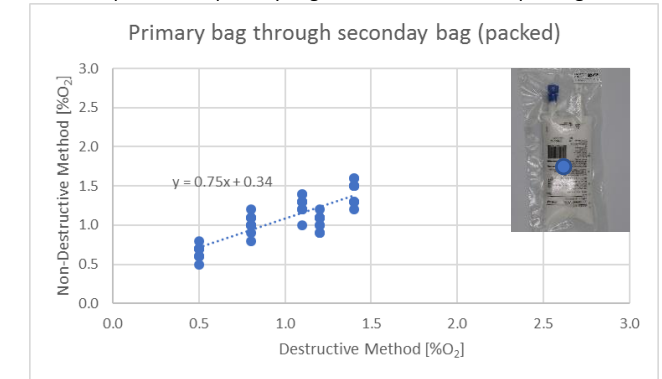
Secondary bag

The secondary bag was measured by doing the measurement in the area between the ports of the packed IV bag-
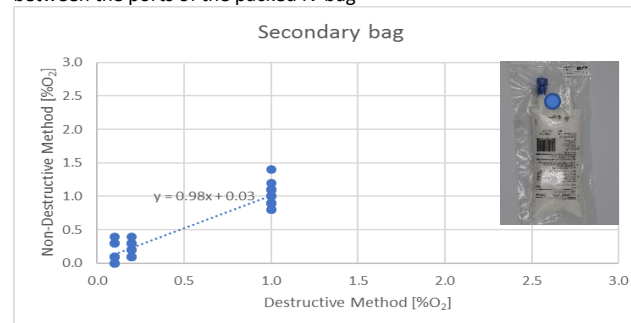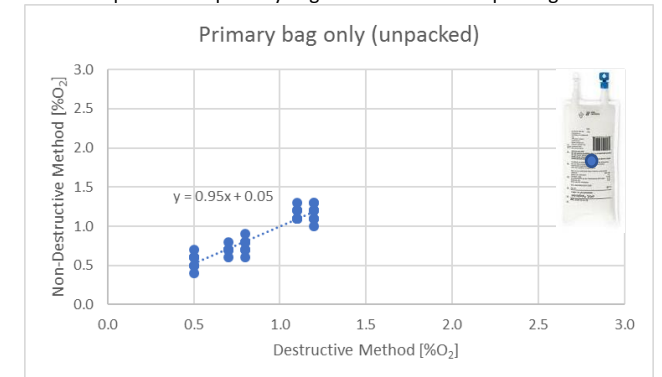

Primary bag through secondary bag

The headspace of the primary bag was tested without unpacking it.

Primary bag only, without secondary bag

The headspace of the primary bag was tested after unpacking it.

Correlation measuring packed/unpacked

The average of the measured values of each primary bag in packed and unpacked condition is shown below. The good correlation is demonstrated.