

Application Note

IV Bag Headspace Oxygen Measurements

Gasporox presents GPX1500 Film Pharma for headspace oxygen measurements of pharmaceutical IV-bags and pouches.

IV bags are frequently used in the pharmaceutical packaging. Some products require low oxygen levels to keep the shelf life. Therefore, the oxygen is removed during packaging by purging the bag with nitrogen to displace the residual air in the IV bag. A statistical check is a part of the GMP procedures to assure the quality. Traditional methods require a gas sample to be extracted from the IV bag's headspace. Such methods are destructive, and the product needs to be rejected. This process generates relevant cost and a risk of operator errors.

The Gasporox's non-destructive instrument GPX1500 Film Pharma eliminates these drawbacks. This laser-based Headspace Analyzer (HSA) method does not require any special sample preparation.



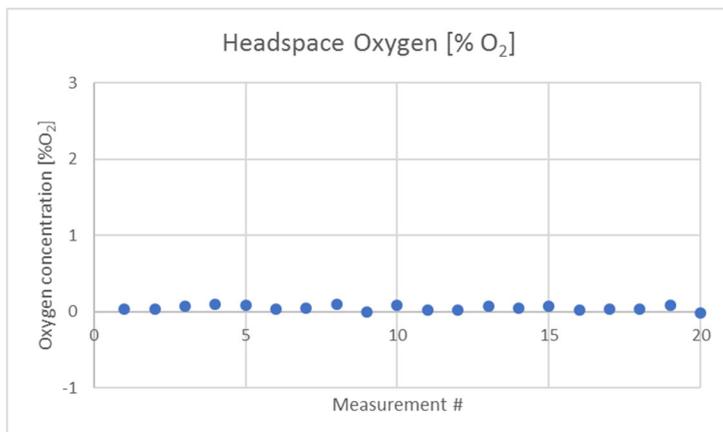
GPX1500 Film Pharma
Easy to use oxygen HSA for IV bags and other pharmaceutical pouches

- Laser based measurement
- Supports bag range 100-5000 ml
- Possible to measure low headspace >3 ml
- GMP Compliant

Application Example

The headspace of the primary bag is measured without removing the secondary bag. The IV bag is placed in the sample position, the measurement is triggered using the touch screen and after a few seconds the headspace oxygen is displayed. The IV bag is removed and measured again. 20 measurements are performed, and the values are recorded. The IV bag is not damaged or altered and can be returned to the production.

Product: IV bag, 250 ml
 Gas: Residual O₂ in N₂
 Measurement time: 4 seconds
 Sample handling: Placing the IV bag manually on the instrument



Performance: All values are within a band of $\pm 0.08\%$ O₂.

Supported Packages

- Large and small volume parenteral
- Flexible film containers
- Multi-chamber, primary and secondary bags can be measured
- Transparent measurement window >10x30 mm needed
- Content examples: Lactated ringers, Saline solutions, dextrose, colloid fluids and more.