GPX Series Instruments

GASPOROX
LASER SENSOR PACKAGE SOLUTIONS

Application Note

Low Headspace Volume Evaluation

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 minimum required headspace gas volume for measuring the oxygen was evaluated. For testing, two types of IV bags have been used. Both have a specified product volume of 250 ml. One contains a clear solution and the second contains a white nutrition liquid. The normal headspace volume is approx. 50 ml for both types of bag.

For testing, the complete headspace of the bag was removed using a syringe. After having the headspace free IV bag, it was placed on the GPX1500 Film Pharma to measure the headspace oxygen concentration. Obviously, the instrument alarmed because the laser was blocked by the liquid.

A syringe was used to inject air in volume steps of 1 ml. The bubble was placed in the position of measurement, and it was checked if a reliable measurement is possible. At 2 ml, the bag with the white nutrition liquid was possible to measure correctly, while it was not always possible to measure the clear liquid. At 3 ml, it was always possible to measure the headspace reliably in both cases.