

INTRODUCTION

The development of advanced therapy medicinal products (ATMPs) has challenged healthcare facilities to adapt in order to manage their reconstitution. In this context, the use of isolators for ATMPs preparation remains limited today due to the potential incompatibility of the primary packaging with hydrogen peroxide (H₂O₂)-based biocontamination.

The purpose of this study is to assess a method that would allow the detection of H₂O₂ in order to identify potential permeability in CellSeal® vials (made of cyclic olefin copolymer (COC)).

METHOD

- The three replicates were analysed for each vial using the Thermo Scientific® Pierce™ Quantitative H₂O₂ Kit. The limit of detection (LOD = 1.5 µM) and limit of quantification (LOQ = 5 µM) were determined using the method based on the standard deviation of the blank.
- Absorbance was measured at 560 nm using a Jenway 6850 UV/visible spectrophotometer.
- A 5-point standard curve ranging from 15 to 100 µM was prepared for each experiment using Perox 35® solution diluted in sterile water.
- 11 bottles filled with water were tested. Each bottle underwent a decontamination cycle using Perox 35® at the isolator inlet. The tests were conducted over 6 days.



RESULTS

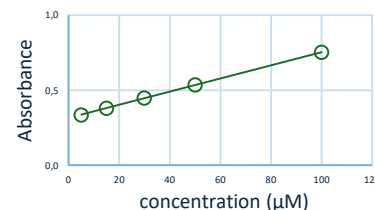
From the 11 vials tested (n=11x3):

❑ Per 4 vials: no H₂O₂ detected (~37%).

❑ For 7 vials: H₂O₂ was detected (values > LOD) (~63%).

❑ This was quantifiable (value > LOQ) for only 3 vials, with a mean of

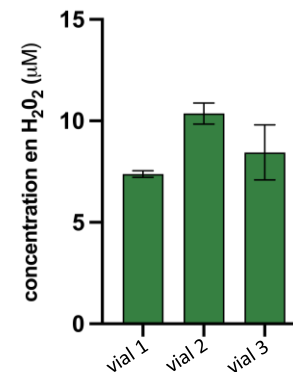
8.7 µM (±1.5):



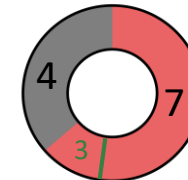
standard curve

$r^2 = 0,9999$

$y = 0,0044x + 0,3146$



H₂O₂ concentration (µM) for each vial



DISCUSSION/CONCLUSION



This method is **effective** and **easily applicable**.



Suitable method for detecting H₂O₂.



Evidence of non-systematic quantification of a low concentration of H₂O₂, in 3 out of 11 vials.



Results should be interpreted with caution for LODs < values < LOQs due to the variability in estimated concentrations.

This preliminary study needs to be confirmed with a larger number of vials in order to conclude that a true detection has occurred and to properly interpret the results.

