OXYNOV® & PharmaKeep®



Colorcon®

Working Together for a Healthier World

OXYNOV® & PharmaKeep®

Use of PharmaKeep® Oxygen Absorbers with OXYNOV® Barrier Bottles

In healthcare OXYNOV® barrier bottles have been developed to support the shelf life of oxygen sensitive drugs. PharmaKeep® capsules and packets are an innovative line of polymer-based oxygen scavengers, developed and distributed jointly by Colorcon (formerly Airnov) and Mitsubishi Gas Chemical Company, Inc. (MGC). PharmaKeep® also adsorbs moisture as it contains desiccant.

Combining OXYNOV bottles and PharmaKeep® oxygen scavengers should be evaluated for performance and headspace inside the packaging, the environmental conditions, possible nitrogen flushing and the use of closure with an induction seal.

To optimize use of OXYNOV bottles and PharmaKeep®, a matrix has been determined to confirm the quantity of oxygen scavengers to be added in each bottle size, according to the following criteria:

- Specifications of OXYNOV barrier bottles (oxygen transmission rate [OTR])
- Specifications of PharmaKeep® products (oxygen absorption}
- ICH conditions (20°C/65% RH; 25°C/60% RH; 30°C/75% RH; 40°C/75% RH)
- Expected shelf life of 3 years (oxygen concentration< 0,7%)
- No use of nitrogen flush inside the bottle
- Nominal headspace of 50% inside the packaging (initial air containing 20.8% of oxygen; headspace
- is calculated by difference between total overflow of the bottle minus volume of drugs in the bottle).

If some criteria are different, please request a specific study to evaluate the impact on the performance of the oxygen protective solution.

OTR of OXYNOV bottles (cc/pack.day.1 atm):

(evaluated at 20°C/65% RH, 100% oxygen)

- BTI 40 cc: 0.00364
- BTI 60 cc: 0.0043
- BTI 100 cc: 0.0057
- BTI 150 cc: 0.0072
- BTI 200 cc: 0.0072
- BTI 400 cc: 0.0106

OXYNOV Absorption Capacity of PharmaKeep products:

(evaluated at 25°C, 7 days)

- Capsule CD-1 G & Packet KD-10S: > 10 ml oxygen
- Capsule CD-2.15G & Packet KD-20: >20 ml oxygen

Recommendation for use:

Applicable for evaluation at 20°/65% RH; 25°C-60% RH; 30°C/75% RH; 40°C/75% RH)

PharmaKeep® to be used inside of OXYNOV Bottles

OXYNOV Bottles	Capsule	Packets
40 cc	1 X CD-1G	1 X KD-10S
60 cc	1 X CD-1G	1 X KD-10S
100 cc	1 X CD-1G	1 X KD-10S
200 cc	1 X CD-2.15G	1 X KD-20
400 cc	1 X CD-2.15G	1 X KD-20

This recommendation does not take into account the moisture content of the drug and the evaluation of the relative humidity level inside the bottle. For evaluation using any other criteria, please contact your Colorcon specialist for a specific predictive evaluation using the STABLUS® Predictive Shelf Ute Simulation.

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