



# Pharmaceutical Stability Products











**AGELESS<sup>®</sup>**  
Oxygen Absorbers

**PharmaKeep<sup>®</sup>**  
Oxygen Absorbing Desiccant






# Line-up of Medical and Pharmaceutical Use Oxygen Absorbers

## [Various Types for Various Purposes]

Main Application	Photographs	Types	Detailed Applications	Features	Usable water activity level	Oxygen Absorption Time
For High Moisture Products		SS-MBC	High moisture products · IV solution in plastic bags	· FDA 21CFR Compliant · DMF Registered	0.65 ~ 0.95	Within 24hrs (25°C/40 ~ 60%RH)
		ZR-5	High moisture products · IV solution in plastic bags	· Quick O <sub>2</sub> absorption · Heat resistant · FDA 21CFR Compliant · DMF Registered		Able to lower the oxygen level of 300ml of air to less than 2% within 30 minutes (25°C/40-60%RH)
		ZPT-MBC	High moisture products · IV solution in plastic bags · Syringes · Ampules	· FDA 21CFR Compliant · DMF Registered · EU FCM Compliant		Within 48hrs (25°C/0%RH)
For Mid-Level Moisture Products		ZM	· Pills and Powders	· FDA 21CFR Compliant · DMF Registered	0.3 ~ 0.65	Within 14days (25°C/40 ~ 60%RH)
		T	· Pills and Capsules · Small and narrow packaging	· Blister pack size	0.3 ~ 0.65	Within 7days (25°C/40 ~ 60%RH)
For Low moisture products For medical instrument		KD	· Pills and Powders	· FDA 21CFR Compliant · DMF Registered	0.3 and under	Within 7days (25°C)
		CD	· Pills and Powders · Medical Instruments	· Canister type · FDA 21CFR Compliant · DMF Registered		
Oxygen Indicator		EYE - LS	· Oxygen Indicator	· Tablet type	0.10 ~ 0.99 (5 ~ 35°C)	—
		EYE - UYR	· Oxygen Indicator (adhesive sheet)	· Paper type	0.70 ~ 0.90 (15 ~ 35°C)	—
High-Barrier Bottle (OXYBarrier™)		OXB	· Pills and Powders	· FDA 21 CFR Compliant · DMF Registration in progress · High gas barrier protection	—	—

# Oxygen Absorbers for high moisture products

- Deterioration of liquid pharmaceuticals through oxidation can be prevented even when stored in plastic containers.
- Nitrogen flushing lowers the initial oxygen level in a package but cannot protect the product from oxygen that permeates the packaging after it has been sealed.
- Able to absorb dissolved oxygen from liquid products.

Type	Photographs	Features	Oxygen Absorption Time	
SS-MBC		<ul style="list-style-type: none"> <li>• High moisture products (IV solution in plastic bags)</li> <li>• FDA 21CFR Compliant</li> <li>• DMF Registered</li> </ul>	Within 24hrs (25°C/40-60%RH)	
ZR-5		<ul style="list-style-type: none"> <li>• High moisture products (IV solution in plastic bags)</li> <li>• Quick O<sub>2</sub> absorption</li> <li>• Heat resistant</li> <li>• FDA 21CFR Compliant</li> <li>• DMF Registered</li> </ul>	Able to lower the oxygen level of 300ml of air to less than 2% within 30 minutes (25°C/40-60%RH)	
ZPT-MBC		<ul style="list-style-type: none"> <li>• High moisture products (pre-filled syringes and ampules, and IV solution in plastic bags)</li> <li>• FDA 21CFR Compliant</li> <li>• DMF Registered</li> <li>• EU FCM Compliant</li> </ul>	ZPT-20MBC,ZPT-30MBC, ZPT-50MBC,ZPT-100MBC, ZPT-200MBC	Within 48hrs(25°C/40-60%RH)
			ZPT-300MBC,ZPT-500MBC	Within 72hrs(25°C/40-60%RH)
			ZPT-1000MBC	Within 96hrs(25°C/40-60%RH)
			ZPT-2000MBC	Within 120hrs(25°C/40-60%RH)
			ZPT-3000MBC	Within 144hrs(25°C/40-60%RH)

Type	Variety	O <sub>2</sub> Absorption capacity(ml)	Size(mm)	Quantity		Handling Time in Open Air (25°C)
				Case (Loose) (pieces per bag x bags per case)	Case (Roll) (pieces per roll x rolls per case)	
SS-MBC	SS-100MBC	100	45 × 40	3000 (100x30)	3000 (1500 x 2)	Within 2 hrs for products with Aw0.65-0.95
	SS-200MBC	200	45 × 55	2000 (100 x 20)	1500 (750 x 2)	
	SS-300MBC	300	60 × 65	1500 (100 X 15)	-	
	SS-400MBC	400	60 × 70	1000 (100 × 10)	-	
	SS-500MBC	500	60 × 75	1000 (100 × 10)	1000 (500 x 2)	
ZR-5	ZR-5	• See Description Above	60 × 75	1000 (100 X 10)	-	Within 30 min for products with Aw0.65-0.95
ZPT-MBC	ZPT-20MBC	20	40 × 30	12000 (400 X 30)	-	Within 4 hrs for products with Aw0.65-0.95
	ZPT-30MBC	30	40 × 35	8000 (200 X 40)	8000(4000 x 2)	
	ZPT-50MBC	50	40 × 40	6000 (200 X 30)	6000(3000 x 2)	
	ZPT-100MBC	100	45 × 40	3000 (100 X 30)	3000(1500 x 2)	
	ZPT-200MBC	200	45 × 55	1500 (100 X 15)	1500(750 x 2)	
	ZPT-300MBC	300	60 × 60	1500 (100 X 15)	1500(750 x 2)	
	ZPT-500MBC	500	60 × 70	1000 (100 X 10)	1000(500 x 2)	
	ZPT-1000MBC	1000	100 × 65	500 (50 X 10)	-	
	ZPT-2000MBC	2000	100 × 90	250 (25 X 10)	-	
ZPT-3000MBC	3000	100 × 105	200 (20 X 10)	-		

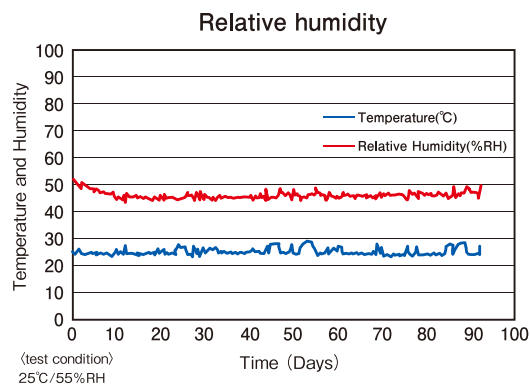
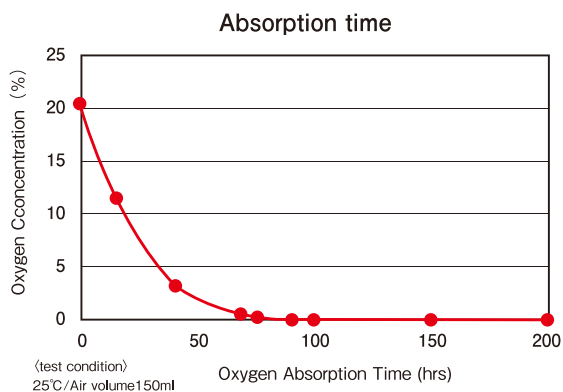
## AGELESS® Storage Method and Guarantee Period


- Store AGELESS packed in carton boxes at room temperature (no higher than 30°C even in summer) with care to avoid exposure to direct sunlight.
- The guaranteed effectiveness period is 6 months after shipment.
- ⚠️ • AGELESS absorbs oxygen when in contact with ambient air. In the event that AGELESS is stored improperly or left in contact with ambient air for too long, the oxygen absorber will be unable to exhibit the desired effect. Strictly abide by the correct storage and handling methods in order to ensure maximum effectiveness.
- ⊘ • AGELESS cannot be reused because it will lose effectiveness after a single use.

# For Non-Liquid Products

## ● AGELESS® ZM for mid-level moisture products (pills and powders)

- AGELESS ZM prevents deterioration of pharmaceutical products by oxygen and does not transfer moisture to the product.
- High Oxygen absorption performance in a small sachet.
- FDA 21CFR Conformed




Type	Photograph	Main Application and Features	Oxygen Absorption Time
ZM		<ul style="list-style-type: none"> <li>• For mid-level moisture products (pills and powders)</li> <li>• FDA 21CFR Compliant</li> <li>• DMF Registered</li> </ul>	Within 14days (25°C/40 ~ 60%RH)

Type	Varieties	O <sub>2</sub> Absorption Capacity (ml)	Size (mm)	Quantity (pieces per bag x bags per case)	Handling time in open air (25°C)
ZM	ZM-1	100	40×20	8000 (200×40)	Within 4hrs

## ● AGELESS® T for mid-level moisture products (pills and capsules)

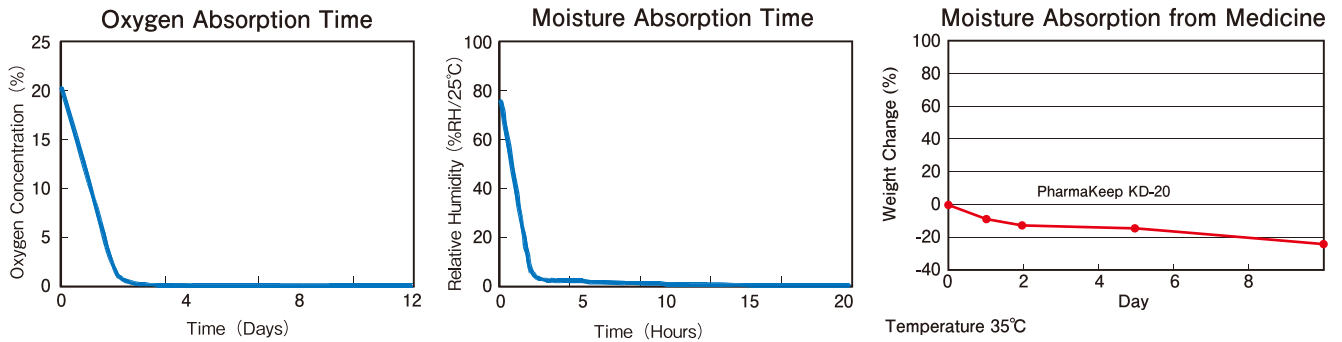
- AGELESS T prevents deterioration of pharmaceutical products by oxygen and does not transfer moisture to the product.
- Easy insertion due to blister pack size.

Type	Photograph	Main Application and Features	Oxygen Absorption Time
T-N		<ul style="list-style-type: none"> <li>• For mid-level moisture products (pills and capsules)</li> <li>• For bottles and narrow packaging</li> <li>• Blister pack size</li> </ul>	Within 7days (25°C/40 ~ 60%RH)



Type	Varieties	O <sub>2</sub> Absorption Capacity (ml)	size (mm)	Quantity (pieces per bag x bags per case)	Handling time in open air (25°C)
T-N	T-10N	10	Diameter φ 16.1×Height 7.1	10000 (500×20)	Within 1hr

## PharmaKeep® for Low moisture products (pills and powders)

- Does not need moisture to absorb oxygen.
- Moisture does not transfer to pharmaceutical products so medical components will maintain efficacy.
- Absorbs both oxygen and moisture to simplify pharmaceutical packaging.



Above data are MGC's measurement values. Results are dependent on the conditions

Type	Photographs	Main Application and Features	Oxygen Absorption Time
KD		<ul style="list-style-type: none"> <li>• For low moisture products (pills and capsules)</li> <li>• FDA 21CFR Compliant</li> <li>• DMF Registered</li> </ul>	Within 7days(25°C)
CD		<ul style="list-style-type: none"> <li>• For low moisture products (pills and capsules)</li> <li>• Canister type</li> <li>• FDA 21CFR Compliant</li> <li>• DMF Registered</li> </ul>	

Type	Varieties	O <sub>2</sub> Absorption Capacity (ml)	Size (mm)	Quantity (pieces per bag x bags per case)	Handling time in open air (25°C)
KD	KD-10S	10	50 × 18.5	5000 (50 × 100)	Within 3hrs (25°C/50%RH)
	KD-20	20	62 × 26	4000 (400 × 10)	
	KD-20R	20	62 × 26	4000 (2000 × 2) <sup>1)</sup>	
CD	CD-1G	10	13.9(φ) × 17.3	9000 (1000 × 9)	
	CD-2.15G	20	17.9(φ) × 22.5	4500 (500 × 9)	

1) Roll type (pieces per roll x rolls per case)

### Guaranteed Effectiveness Period

Sachet type: 12 months after shipment

Canister type: 18 months after production

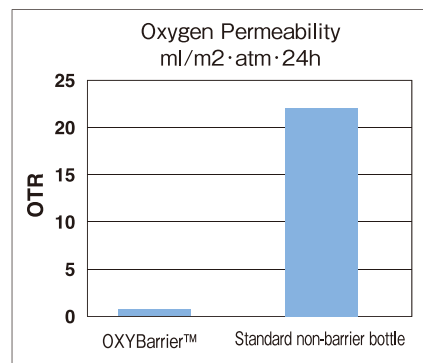
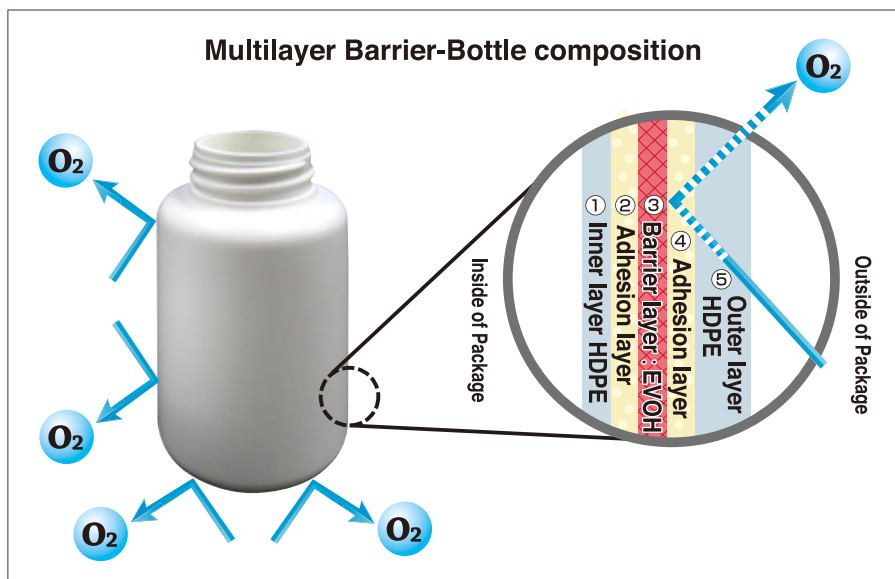
※Once the master bag has been opened, all oxygen absorbers must be used.

PhramaKeep® canister type is not under MGC's ISO9001 QA system.

# For Non-Liquid Products

## ● OXYBarrier™

- Prevents degradation of pharmaceuticals by stopping oxygen permeation through the bottle.
- Possible to maintain the efficacy of pharmaceutical products when combined with an oxygen absorber to ensure a long shelf life.
- Very low OTR allows for use of a smaller oxygen absorber.



Oxygen Permeability	OXYBarrier™	Standard non-barrier bottle
OTR (ml/m <sup>2</sup> · atm · 24h)	0.5	22
100ml Volume Bottle (ml/year)	2.5	31.4

※25°C/40% ~ 60%RH

Moisture Permeability	OXYBarrier™
MVTR (g/m <sup>2</sup> · 24h)	0.1
100ml Volume Bottle (g/year)	0.5

※Storage condition : 25°C100%RH with 10g silica gel

Variety	Volume (ml)	Overflow Capacity(ml)	Mouth diameter of bottle(mm)	Diameter(mm φ) × Height (mm)	Quantity (bottles/case)
OXB - 30	30	41	19.1	37.8 × 57.8	600
OXB - 35	35	48	25.7	38.1 × 60.8	600
OXB - 40	40	51	25.7	37.8 × 60.6	600
OXB - 60	60	71	25.7	39.8 × 74.9	450
OXB - 100	100	116	25.3	48 × 83.5	250

OXYBarrier™ Bottle is not under MGC's ISO9001 QA system.

# How to use oxygen absorbers

- Oxygen absorbers can be combined with a high gas barrier packing material to absorb the oxygen within an airtight package and maintain an oxygen free condition for a certain period of time.

This page outlines how to use oxygen absorbers correctly.

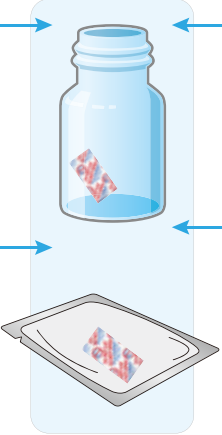
### Four conditions to maintain an oxygen free condition

**Condition 1** Use packing material with a high gas barrier

In order to maintain an oxygen free condition for a certain period of time, select packing material with a high resistance to oxygen permeability, such as plastics, trays, metal cans and glass bottles.

**Condition 3** Create a perfect seal with a sealing machine

The container must be completely sealed to maintain an oxygen free condition. A heat sealer can be used to seal the container.



**Condition 2** Select oxygen absorbers that suit the product characteristics and volume of packing

To ensure that container is deoxygenated within the required time, select a type of oxygen absorbers that suits the product characteristics and packaging form, and select the size that suits the amount of oxygen in the packaging

**Condition 4** Correct handling of Oxygen absorber

Inappropriate handling of the oxygen absorbers can render them useless. Handling conditions differ according to the type, so the conditions for sealing, use and storage explained in the instruction manual should be followed promptly and accurately.



### Final Packaging Tests of Products with Oxygen Absorbers

During preliminary tests with oxygen absorbers the following should be considered: packaging headspace, packaging permeation, possible leakages at the packaging closure and possible presence of defects in the packaging itself.

- In order to keep the inside of the container in an oxygen free state for a certain amount of time, it is necessary to choose packaging material with low oxygen permeability.
- ⚠ Tests should be performed under actual conditions to check the packaging material.
- When opening the carton box, avoid using a sharp edge as there is a possibility of damaging the master bags.
- The oxygen absorbers are vacuum packed. If you hold a master bag on one end, the packets should not slide.
- In the event that the packets slide before opening, do not use the oxygen absorbers in that master bag. It is possible that a pinhole has occurred during transportation and the oxygen absorbers are no longer good.

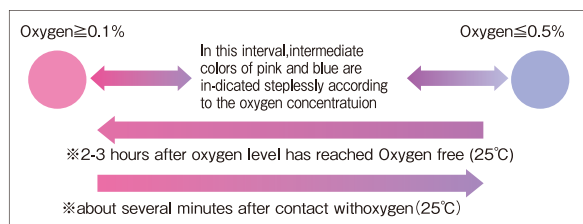
## AGELESS-EYE® Oxygen Indicator

- It is an in-package monitor which indicates the performance of oxygen at a glance.

Type	Photographs	Size (mm)	Quantity (pieces per bag x bags per case)	Use conditions
Tablet type		41 × 33	6000 (500 × 12)	5 ~ 35°C, Aw 0.10 ~ 0.99
Paper type		16 × 10	30000 (10000 × 3 rolls)	15 ~ 35°C, Aw 0.70 ~ 0.90 Ageless pasting is possible.

The AGELESS-EYE is an in-package monitor which indicates the presence of oxygen at a glance. Please use it for testing purposes only.

※AGELESS-EYE is not FDA 21 CFR Conformed.



### AGELESS EYE® Storage Method and Guarantee Period

- ⚠ AGELESS-EYE® is delivered at room temperature. Upon arrival, immediately place in a refrigerator and keep at no higher than 15°C with care to prevent exposure to light

- The oxygen concentration and time required for discoloration are merely an estimate and not guaranteed values.
- Discoloration takes place more slowly at low temperatures

Type of AGELESS-EYE®	Guarantee period	Use condition
EYE-LS	6 months after shipment	5~35°C, AW 0.10~0.99
EYE-UJR	2 months after shipment	15~35°C (for use with Aw 0.70~0.90)

# PharmaKeep® information

## 1. Out-gases

PharmaKeep generates a small amount of out-gases. It is difficult for us to confirm every effect of the out-gases with each customer's products. We would like to ask our customers to confirm the effects of PharmaKeep through tests with actual products at actual conditions.

Table 1: Out-gases from PharmaKeep PACKET KD-20 after oxygen absorption \*1

Out gases	Gas concentration (per 1 peace/100ml air)	Out gases	Gas concentration (per 1 piece/100ml air)
Carbon dioxide	0.5 % <sup>*2</sup>	Methane	11 ppm <sup>*4</sup>
Hydrogen	0.1 % <sup>*2</sup>	Ethane	3 ppm <sup>*4</sup>
Formaldehyde	N.D. <sup>*3</sup>	Propane	N.D. <sup>*4</sup>
Acetaldehyde	N.D. <sup>*3</sup>		

\*1) Typical analytical data of PharmaKeep packet KD-20 (Lot. No.3121ES). This data is not guaranteed value.

\*2) Analyzed by GC-TCD / One KD-20 with 100 ml of air for 7 days at 25 °C.

\*3) Analyzed by gas detector tube system (GASTEC) / Fifteen pieces of KD-20 with 1,500 ml of air for 7 days at 25 °C.

\*4) Analyzed by GC-FID / One KD-20 with 100 ml of air for 7 days at 25 °C.

## 2. Smell

PharmaKeep products may generate a slight odor after oxygen absorption. We recommend that customers confirm the effects of PharmaKeep through tests with their products.

## 3. Adhesion of granules

A small amount of PharmaKeep granules may adhere to the surface of PharmaKeep sachets and canisters. We recommend that customers confirm the effects of PharmaKeep through tests with their products.

## 4. Final Packaging Tests of products with PharmaKeep

During preliminary tests with PharmaKeep, the following should be considered : packaging headspace, packaging permeation, possible leakages at the packaging closure, and possible presence of defects in the drug packaging. Preserved medicine might become oxidized despite using.



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