MGC

Oxygen absorbers
for pharmaceuticals

AGELESS®

Oxygen absorber for liquid pharmaceuticals
Oxygen absorber for solid pharmaceuticals

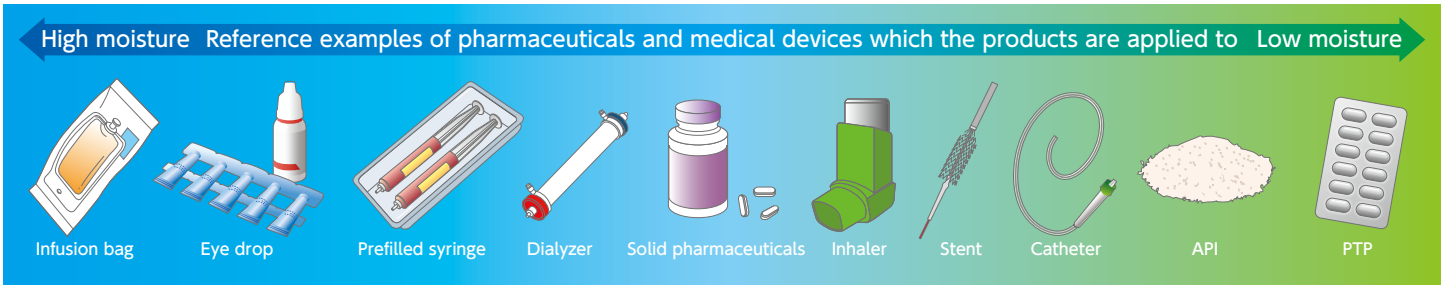
PharmaKeep®

Oxygen absorber with drying function for
solid pharmaceuticals and medical devices

MITSUBISHI GAS CHEMICAL COMPANY, INC.

Lineup of oxygen absorbers for pharmaceuticals

We provide a wide variety of products to maintain the quality of pharmaceuticals and medical devices.

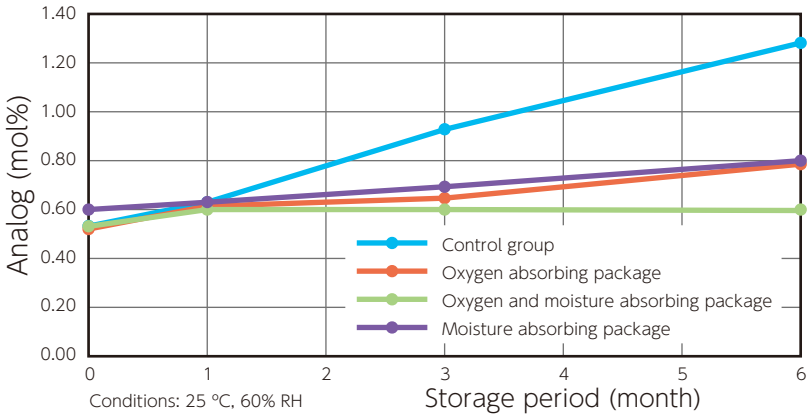


Variety	AGELESS® Oxygen absorber for liquid pharmaceuticals		AGELESS® Oxygen absorber for solid pharmaceuticals with medium moisture content	PharmaKeep® Oxygen absorber for solid pharmaceuticals with low moisture content and medical devices	
Type	FX-PAN page 3.	SS-YMBC page 3.	ZM page 4.	KD page 5.	CD page 5.
Appearance					
Main application	Liquid pharmaceuticals - Infusion bags - Injections		Solid pharmaceuticals Medical devices Supplements	Solid pharmaceuticals Medical devices	
Feature/ Regulation	- Compliance with FDA - Registered in US DMF/ China DMF - Heat resistance	- Compliance with FDA - Registered in US DMF/ China DMF	- Compliance with FDA - Registered in US DMF/ China DMF	- Compliance with FDA - Registered in US DMF/ China DMF	- Canister type - Compliance with FDA - Registered in US DMF
Range to be applied (Activity of water/Aw)	0.65~0.95		0.3~0.65	0.3 or less	
Oxygen absorption time	Within 20 hours (25±2℃/100%RH)	Within 24 hours (25±2℃)	Within 30 days (25±2℃)	Within 7 days (25±2℃)	

Variety	AGELESS EYE® Oxygen indicator		
Type	EYE-LS page 7.	EYE-RS page 7.	EYE-LM page 7.
Appearance			
Main application	Liquid pharmaceuticals - Infusion bags - Injections		
Feature/ Regulation	Resistered in China DMF	- Heat resistance - Compliance with US FDA - Registered in US DMF/ China DMF	Registered in US DMF

Effects of deoxygenated packages

1 Stability of API “azelnidipine”



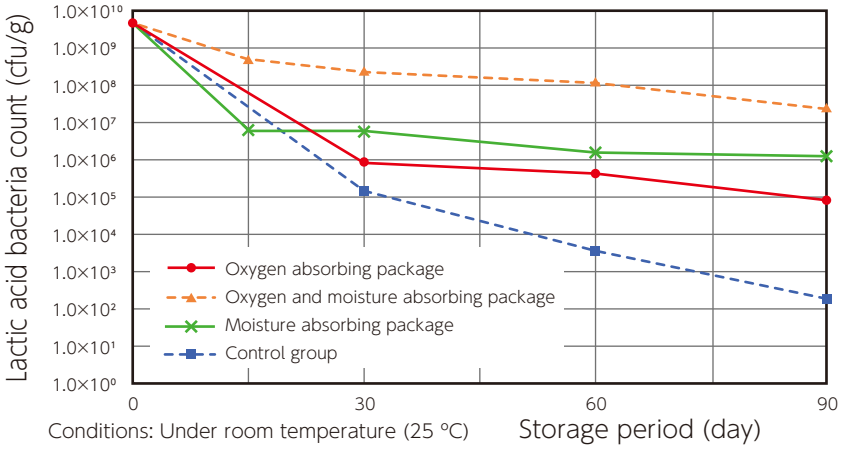
○ The API, azelnidipine, became stable by use of an oxygen and moisture absorbing package

2 Retention of lactic acid bacteria count

■ Initial property

No	Lactic acid bacteria count (cfu/g)
1	2.3×10^9
2	2.7×10^9
3	2.9×10^9

■ Storage test



○ Effect to maintain the lactic acid bacteria count was confirmed in use of an oxygen and moisture absorbing package.

3 Antioxidative effect [DHA, EPA supplement]

		3 months	6 months	9 months	12 months
Oxygen absorbing package	O_2	0.01%or less	0.01%or less	0.01%or less	0.01%or less
	CO_2	0.1%or less	0.1%or less	0.1%or less	0.1%or less
	Smell	○	○	○	○
	POV (meq/kg)	2.4	2	1.9	1.8
	AV (KOHmg/g)	0.1or less	0.1or less	0.1or less	0.1or less
	Vitamin E (mg/100 g)	15.8	15.4	15.3	15.9
Control group	O_2	20.28	19.38	19.03	20.75
	CO_2	0.1	0.1	0.1	0.1
	Smell	+～++	++	+++	+++
	POV (meq/kg)	5.8	8.6	10.1	15
	AV (KOHmg/g)	0.1	0.1	0.1	0.1
	Vitamin E (mg/100 g)	15.5	14.5	13.7	12.9

Note 1): Smell: ○: Normal, + ~ +++: Slightly ~ highly abnormal
Conditions: 35 °C

○ Oxidation of fats and oils and occurrence of an abnormal smell were prevented.

AGELESS® Oxygen absorber for liquid pharmaceuticals

Product

Type	Appearance	Main application	Oxygen absorption time
FX-PAN		Liquid pharmaceuticals - Infusion bags - Injections	Within 20 hours (25±2℃/100%RH)
SS-YMBC			Within 24 hours (25±2℃)

Type	Product Code	Oxygen absorption capacity (mL)	Size (mm)	Quantity		Handling time
				Loose (packets in a bag × bags)	Roll (packets in a Roll × Rolls)	
FX-PAN	FX-100PAN	100	50×41	3,000(300×10)	-	Within 8 hours (25℃/under 70%RH)
	FX-200PAN	200	50×52	1,500(300×5)	-	Within 4 hours (25℃/70%~90%RH)
SS-YMBC	SS-100YMBC	100	45×40	3,000(100×30)	3,000(1,500×2)	Loose types : Within 2hrs for Roll types: 1,000 or more sachets per hour
	SS-202YMBC	200	45×55	2,000(100×20)	2,000(2,000×1)	
	SS-300YMBC	300	60×65	1,500(100×15)	1,500(1,500×1)	
	SS-400YMBC	400	60×70	1,000(100×10)	1,000(1,000×1)	
	SS-500YMBC	500	65×75	1,000(100×20)	1,000(500×2)	

Feature

○ Prevents oxygen-caused deterioration in the quality of liquid pharmaceuticals, even when resin containers are used.

○ Keeps the quality from deteriorating due to slight oxygen entering from the outer container, which cannot be fully removed in a package with an inert gas, such as nitrogen (the oxygen concentration within a container is maintained at 0.1% or less).

○ Absorbs dissolved oxygen from a drug solution.

Regulation

Compliance with FDA

Registered in US DMF/ China DMF

Point

Storage method and guarantee period (unopened outer package only)

* Store the unopened carton box at room temperature (at or below 30 °C even in summer) away from direct sunlight.
* The quality guarantee period is 12 months after shipment.

Notice

When wrongly used, AGELESS® absorbs oxygen in air before packaging and fails to produce the expected effects.

Don't

Used AGELESS® cannot be reused because the effectiveness may be lost.

AGELESS® Oxygen absorber for solid pharmaceuticals with medium moisture content

Product

Type	Appearance	Main application	Oxygen absorption time
ZM-1		Solid pharmaceuticals with medium moisture content Medical devices Supplements	Within 30 days (25±2℃)

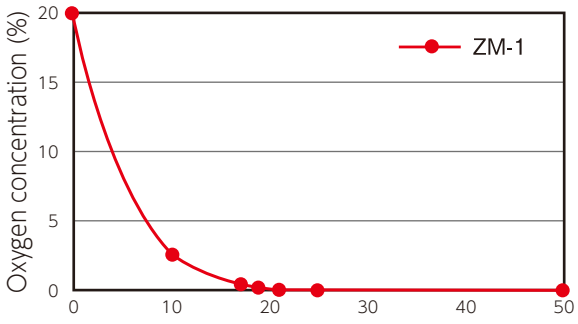
Type	Product Code	Oxygen absorption capacity (mL)	Size (mm)	Loose (packets in a bag × bags)	Roll (packets in a roll × rolls)	Handling time
ZM	ZM-1	100	40×20	8,000 (200×40)	8,000 (4,000×2)	1,000 or more sachets per hour

Feature

○ Prevents oxygen-caused deterioration in the quality of sold pharmaceuticals and also prevents moisture from transferring from the inside of the oxygen absorber to the sold pharmaceutical.

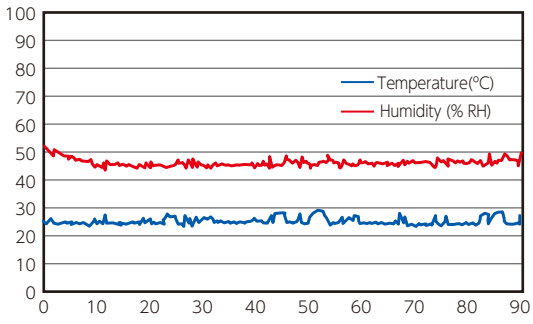
○ Has high oxygen absorbing ability in the small sachet.

■ Oxygen absorbing speed



Conditions: 25 °C, Air volume 40 mL

■ Change in humidity inside the container



Conditions: 25 °C, 55% RH

Regulation

Compliance with FDA

Registered in US DMF/ China DMF

Point

Storage method and guarantee period (unopened outer package only)

* Store the unopened carton box at room temperature (at or below 30 °C even in summer) away from direct sunlight.
* The quality guarantee period is 12 months after shipment.

PharmaKeep® Oxygen absorber for solid pharmaceuticals with low moisture content and medical devices

Product

Type	Appearance	Main application	Oxygen absorption time
KD		Solid pharmaceuticals with low moisture content Medical devices	7 days (25±2℃)
CD			

Type	Product Code	Oxygen absorption capacity (mL)	Moisture absorption capacity (mL)	Size (mm)	Quantity		Handling time
					Loose (packets in a bag × bags)	Roll (packets in a roll ×rolls)	
KD	KD-10S	10	0.07	50×20	4,000 (400×10)	4,000 (2,000×2)	Within 3 hours
	KD-20	20	0.15	62×26	4,000 (400×10)	4,000 (2,000×2)	
	KD-400	400	3.0	135×100	250 (10×25)	-	
CD	CD-1G	10	0.07	13.9ϕ×17.3	6,000 (1,000×6)	-	
	CD-2.15G	20	0.15	17.9ϕ×22.5	3,000 (500×6)	-	

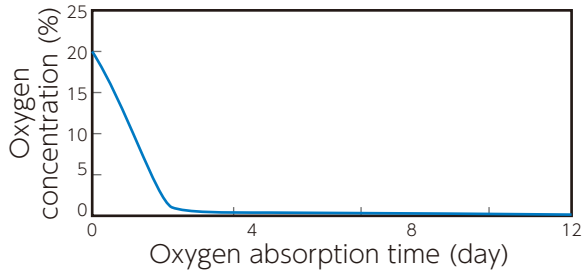
Feature

○ Has no need of moisture in absorbing oxygen.

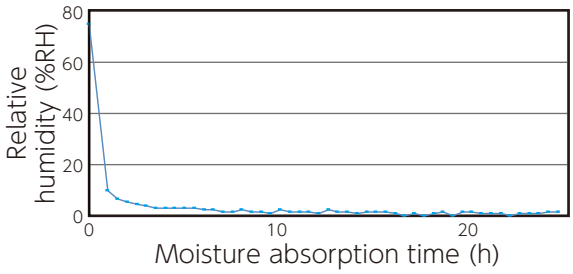
○ Allows to simplify packaging of medical products by integrating oxygen absorbing function with drying function.

○ Prevents moisture from transferring to the pharmaceuticals to protect the active ingredients of dry solid pharmaceuticals against hydrolysis.

■ **Oxygen absorbing speed**



■ **Moisture absorbing speed**



* PharmaKeep®: KD-20, Enclosed air: 100 mL (75% RH); Storage conditions: 25 °C, 60% RH; Package: Aluminum bag

Regulation

KD-type : Compliance with FDA
Registered in US DMF/ China DMF

CD-type : Compliance with FDA
Registered in US DMF

Point

Storage method and guarantee period

* Store the carton box at room temperature away from direct sunlight (at or below 25 °C even in summer).
* The quality guarantee period is 12 and 18 months after shipment for sachet type and after production for canister type, respectively.

(PharmaKeep® canister type is not included in our quality management system, ISO 9001.)

For consideration of PharmaKeep®

1 Out-gases

PharmaKeep® generates a little amount of out-gases. It is difficult for us to confirm every effect of out-gases to each customer's products. We would like to ask our customers to confirm effects of PharmaKeep® by 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 piece/500 ml air)	Out gases	Gas concentration (per 1 piece/500ml air)
Carbon dioxide	0.44%*2	Acetaldehyde	1ppm*3
Carbon monoxide	N.D.*2	Methane	13ppm*4
Hydrogen	0.05%*2	Ethane	10ppm*4
Formaldehyde	1.5ppm*3	Propane	1ppm*4

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

*2) Analyzed by GC-TCD / One piece of KD-20 with 500 ml of air for 14 days at 25 ˚C.

*3) Analyzed by gas detector tube system(GASTEC) / Three pieces of KD-20 with 1,500 ml of air for 14 days at 25 ˚C.

*4) Analyzed by GC-FID / One piece of KD-20 with 500 ml of air for 14 days at 25 ˚C.

2 Smell

PharmaKeep® products may generate smell by oxygen absorption. We recommend that customers confirm effects of PharmaKeep® by tests with their products.

3 Adhesion of granules

Small amount of PharmaKeep® granules may adhere to surface of PharmaKeep® sachets and canisters. We recommend that customers confirm effects of PharmaKeep® by tests with their products.

4 Test of final packaging of products with PharmaKeep®

During customers tests with PharmaKeep® should be considered packaging headspace, packaging permeation, possible leakages at the packaging closure, but also possible presence of defects in the drug packaging itself. In case of none estimated leakages, and / or undetected packaging defects, preserved medicine might be oxidized despite of PharmaKeep® presence.

AGELESS EYE® Oxygen indicator

Product

Type	Appearance	Size (mm)	Quantity	Color Change Speed*
EYE-LS		41×33	6,000 (500 packets × 12 bags)	within 24 hours (25±2℃)
EYE-RS		41×33	6,000 (500 packets × 12 bags)	within 1-2weeks (25±2℃)
EYE-LM		35×22	18,000 (500 packets × 36 bags)	within 30hours (25±2℃)

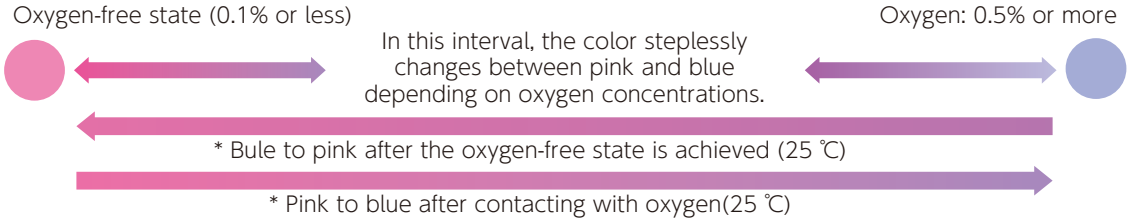
Color Change Speed* :
EYE-LM/LS: Time for each one packet to change color from blue to pink under 0.1% of oxygen or less at 25±2degrees
EYE-RS: Time for each one packet change color from blue to pink after retorting under 0.1% of oxygen or less at 25±2degrees

Feature

○ Allows to visually check the oxygen-free state (oxygen concentration: 0.1% or less) in a container or a package by color-changing.

○ EYE-RS has heat resistance and is available for use under retort conditions, depending on the terms.

Image of color changing



Regulation

EYE-LS : Registered in China DMF
EYE-RS : Compliance with FDA Registered in US DMF/China DMF
EYE-LM : Resistered in US DMF

Point

Storage method and guarantee period of AGELESS EYE®

* AGELESS-EYE® products are delivered by Courier or Air. On arrival, please immediately place them in a refrigerator and keep them at below 15 ℃ with protection from light.
* The quality guarantee period is 6 months after shipment when stored at 15 ℃.

The oxygen concentration and time required for discoloration are rough tandards and not guaranteed. Discoloration occurs more slowly at lower temperatures.

How to use AGELESS-EYE®

- Take out a required quantity from the outer bag.
- Enclose an AGELESS-EYE® together with an oxygen absorber in a package of the product.
- Apply AGELESS-EYE® to the products within 12 hours (operation time). Apply AGELESS-EYE® under the operation environment avoiding direct sunlight and a particularly strong light (brightness: 500 lux or below).
- Performance of AGELESS-EYE® decreases when it is left in air for a long time, exposed to light for a long time, and stored at high temperature (over room temperature).
- AGELESS-EYE® cannot be recused because the discoloration performance gradually decreases.
- After unpackaging of the outer bag of AGELESS-EYE®, enclose self-reacting AGELESS® ZPT or SS type (size: 100 or above) in the bag, seal the bag to make it oxygen-free state with protection from light , and be sure to store it in a refrigerator at or below 15 ℃.

The pink tone of AGELESS-EYE® indicates that oxygen concentration inside of the container is 0.1% or less and does not directly indicate the packaging status or the quality of the product.

Handling of AGELESS®, PharmaKeep®

An oxygen absorber, combined with packaging materials with high gas barrier properties, absorbs oxygen in a sealed container to maintain an oxygen-free condition (oxygen concentration: 0.1% or less) for a certain period. Appropriate method of use and points in packaging with oxygen absorbers are as follows.

Four conditions to achieve oxygen-free state

Condition 1 Prepare packaging materials with high gas barrier properties

Select materials with low oxygen permeability in order to keep the inside of the container oxygen-free for a certain period.
In packaging with oxygen absorbers, materials with high gas barrier properties, including resin bags and bottles, aluminum bags, and glass bottles, are used.

Condition 2 Select oxygen absorbers appropriate for properties of products and packaging containers

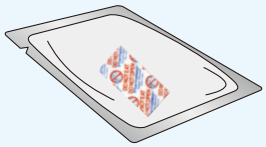
In order to keep the inside of the packaging container oxygen-free within the storage period of the target products, select the type appropriate for properties of products and packaging containers and the size corresponding to the total of the initial amount of oxygen in a packaging container and the amount of oxygen permeating the packaging container within the storage period.

Condition 3 Ensure comeplete sealing using a sealer etc

If a package with an oxygen absorber is not completely sealed, it does not become oxygen-free.
Completely seal the container with a sealer or another tool.

Condition 4 Appropriately handle oxygen absorbers

Misuse of oxygen absorbers results in loss of effectiveness, etc.
Handling conditions of oxygen absorbers depend on their types. Promptly and appropriately open, use, and store them according to the specified conditions.
Once the package is opened, take out and discard the oxygen absorber.



Confirmation by implementation testing of product

Before application of oxygen absorbers, perform implementation test using the finished products to confirm the effects of oxygen absorbers. If the oxygen-free condition is not maintained because of packages, etc. of the finished products with a pinhole made during the distribution process, the pharmaceuticals may be deteriorated by oxidation. In such case, verify whether the pharmaceuticals have negative effects on the human body and then take measures, as appropriate.

- ○ Generally, it is necessary to select materials with low oxygen permeability in order to keep the inside of the container oxygen-free for a certain period.
  * Make sure to perform implementation test to confirm the adequacy of the packaging materials.
- ○ Do not use blades, such as a cutter, to open the carton box.
- ○ The outer bag of packet products is vacuum packaged. Hang the outer bag from one end to confirm that the content does not drop to the other end. When the packets drop to the bottom, do not use them because the outer bag may have a pinhole. If the vacuum in an outer bag is lost when opening the carton box, contact our distributor to replace the outer bag.

Strength as a leading manufacturer in the oxygen absorber industry

1 Dependable business continuity planning (BCP) Stable supply

- Two main production sites located in Japan and Thailand
- Product warehouses in several locations in Japan and abroad

2 Broad product lineup

- Abundant product lineup available for drug dosage forms and their properties
- Products complying with FDA/EU regulations; including products registered in DMF

3 Experienced technical service

- Data acquisition and troubleshooting in AGELESS Service Center

4 Thorough quality control

- ISO 9001 certified
- State-of-the-art equipment and the quality appreciated for many years

5 Achievements in the medical use over the years

- Achievements in supplying the products to many domestic and overseas pharmaceutical manufacturers
- Caring customer service and innovative product development

Research and Development Center of Oxygen Absorbers

Tokyo Techno Park (TTP), Mitsubishi Gas Chemical Company, Inc.

Technical Service of Oxygen Absorbers

AGELESS Service Center, Tokyo Office, MGC AGELESS Company Limited

Production Plant of Oxygen Absorbers

Shirakawa Office, MGC AGELESS Company Limited

Production Plant of Oxygen Absorbers

AGELESS (THAILAND) CO.,LTD.

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