

The logo for Mitsubishi Gas Chemical Company, Inc. (MGC) is displayed in white, bold, sans-serif capital letters on a blue background.

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

AGELESS OMAC[®] Oxygen-absorbing film

OxyBarrier[™] High gas-barrier bottle



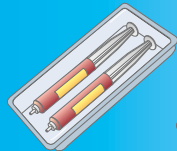













MoistureVanish[™]




AGELESS EYE[®] Oxygen indicator



Lineup of oxygen absorbers for pharmaceuticals

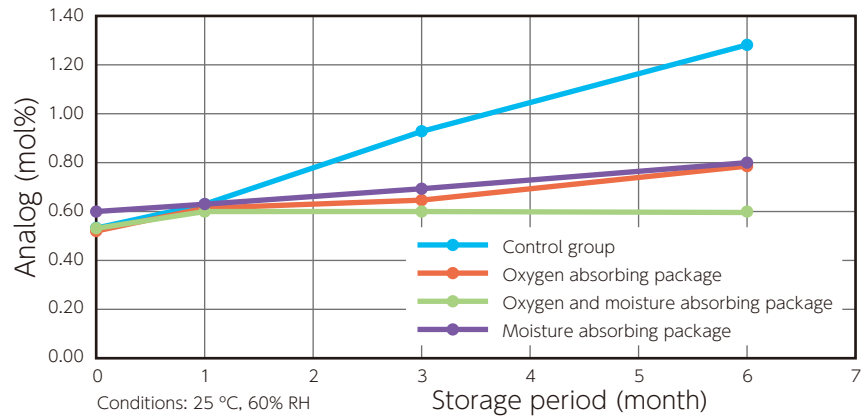
We provide a wide variety of products to maintain the quality of pharmaceuticals and medical devices.

		High moisture						Reference examples of pharmaceuticals and medical devices which the products are applied to		Low moisture	
											
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-MBC page 3.		ZM page 5.		ZM-C page 5.		KD page 7.		CD page 7.
Appearance											
Main application	Liquid pharmaceuticals - Infusion bags - Injections		Solid pharmaceuticals Medical devices Supplements				Solid pharmaceuticals Medical devices				
Feature	- Compliance with FDA - Registered in DMF - Heat resistant		- Compliance with FDA - Registered in DMF		- Compliance with FDA - Registered in DMF		- Canister type - Compliance with FDA - In preparation for registration for DMF		- Compliance with FDA - Registered in DMF		- Canister type - Compliance with FDA - Registered in 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°C/100%RH)		Within 24 hours (25±2°C/40~60%RH)		Within 30 days (25±2°C/40~60%RH)		Within 7 days (25°C)				

Variety	AGELESS EYE® Oxygen indicator	AGELESS OMAC® Oxygen-absorbing film	OxyBarrier™ High gas-barrier bottle
Type	EYE-LS page 9.	OMAC page 4.	OXB page 6.
Appearance			
Main application	Liquid pharmaceuticals - Infusion bags - Injections	Liquid pharmaceuticals - Infusion bags - Eye drops	Solid pharmaceuticals Supplements
Feature	Tablet type	- Oxygen absorbing function - Compliance with FDA - Registered in DMF	- Oxygen Barrier bottle - Compliance with FDA - In preparation for registration for DMF
Note	Range to be applied (Aw) 0.10~0.99 (5~35°C)	Oxygen absorption capacity 0.1~0.5ml/cm ²	Oxygen permeability 0.5ml/m ² ·atm·24h ※25°C/40~60%RH Water vapor permeability 0.1g/m ² ·24h ※25°C/100%RH With 10g silica gel

Effects of deoxygenated packages

1 Stability of API "azelnidipine"



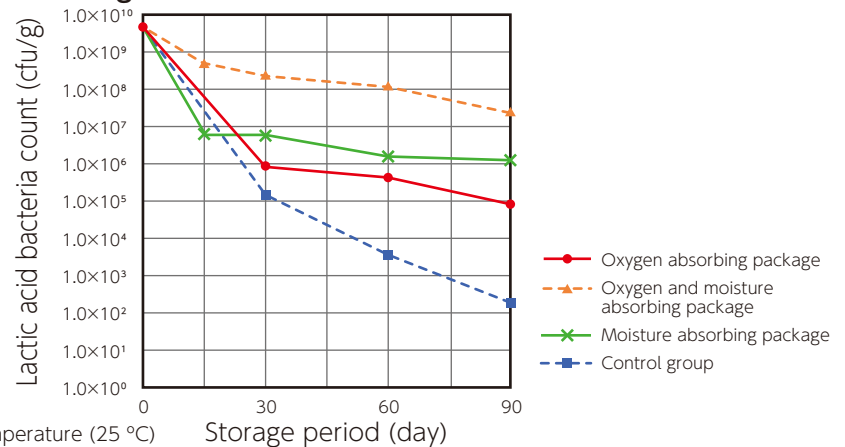
- The APT, azelnidipine, became stable by use of an oxygen and moisture absorbing package

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)	0.1 or less	0.1 or less	0.1 or less	0.1 or 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
Storage test: 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°C/100%RH)
SS-MBC			Within 24 hours (25±2°C/40~60%RH)

Type	Product No	Oxygen absorption capacity (mL)	Size (mm)	Quantity		Handling time
				Loose (packets in a bag × bags)	Roll (packets in a roll × rolls)	
FX-PAN	FX-50PAN	50	40×37	6,000(500×12)	-	Within 8 hours (25°C/under 70%RH) Within 4 hours (25°C/70%~90%RH)
	FX-100PAN	100	50×41	3,000(300×10)	-	
	FX-200PAN	200	50×52	1,500(300×5)	-	
SS-MBC	SS-100MBC	100	45×40	3,000(100×30)	3,000(1,500×2)	Loose types : Within 2hrs for Products with Aw 0.65-0.95 Roll types: 1,000 or more sachets per hour
	SS-200MBC	200	45×55	2,000(100×20)	2,000(2,000×1)	
	SS-300MBC	300	60×65	1,500(100×15)	-	
	SS-400MBC	400	60×70	1,000(100×10)	-	
	SS-500MBC	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.

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 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 OMAC[®] Oxygen-absorbing film for liquid pharmaceuticals

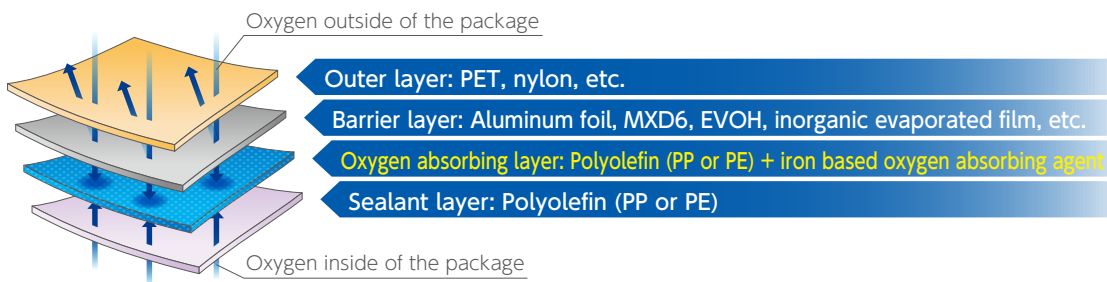
Product

Type	Appearance	Main application	Oxygen absorption capacity
OMAC		Liquid pharmaceuticals - Infusion bags - Eye drops	0.1~0.5ml/cm²

Type	Thickness of film (μ)	Handling time	Guarantee period
OMAC	90~130 μ	Within 24 hours after the outer package is opened. (23 °C / 60% RH)	6 months after production

Film structure

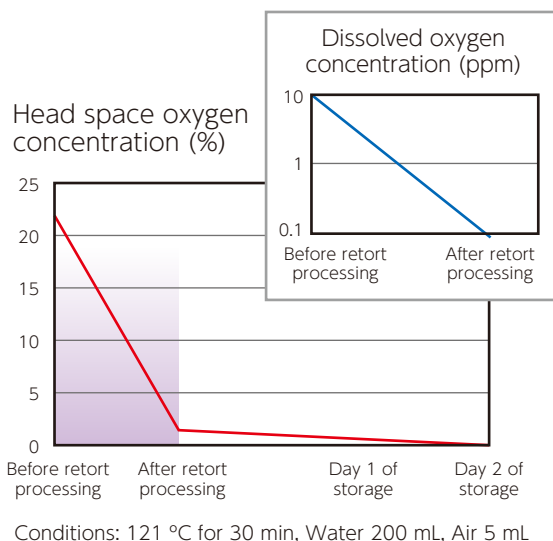
○ AGELESS OMAC[®] film has a special structure composed of four layers.



Feature

- Absorbs oxygen from a container.
- Removes dissolved oxygen from the contents of a container.
- Saves the time and effort of inserting oxygen absorbers.
- Available as bag and roll products.

■ For heat application



■ For non-heat application

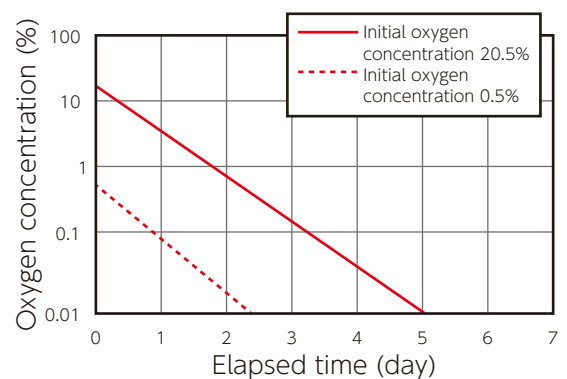




Figure: Oxygen absorbing speed under the condition of non-heating of PE-based OMAC (25 °C)
Film size: 264 cm² (110 × 120 mm, both sides)
Air volume of 40 cc, 90% RH, 25 °C

* The above data are our measurements and not guaranteed.

Product

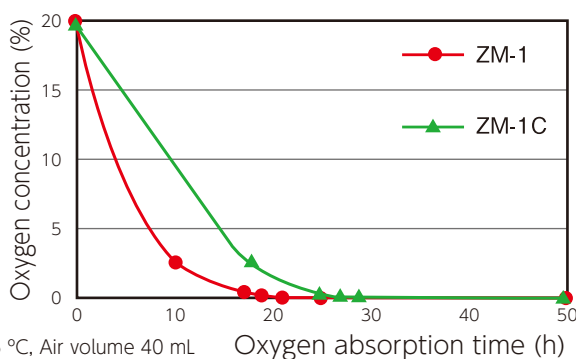
Type	Appearance	Main application	Feature	Oxygen absorption time
ZM-1		Solid pharmaceuticals with medium moisture content Medical devices Supplements	Compliance with FDA Registered in DMF	Within 30 days (25±2°C/40~60%RH)
ZM-1R				
ZM-1C (Development product)			Canister type	

Type	Product No.	Oxygen absorption capacity (mL)	Size (mm)	Loose (packets in a bag X bags)	Roll (packets in a roll X rolls)	Handling time
ZM	ZM-1	100	40×20	8,000(200×40)	-	Within 4 hours
	ZM-1R	100	40×20	-	8,000(4,000×2)	1,000 or more sachets per hour
	ZM-1C	100	14.0φ×18	8,000(800×10)	-	Within 4 hours

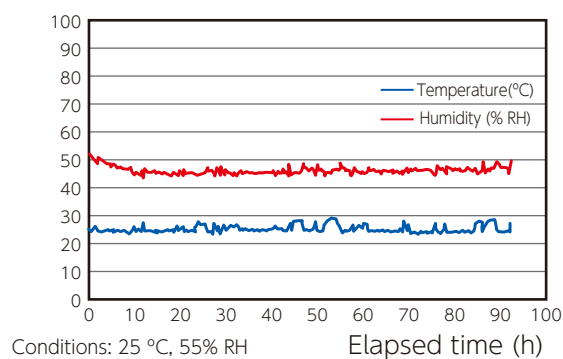
Feature

- 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



■ Change in humidity inside the container




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.

OxyBarrier™ High gas-barrier bottle

Product

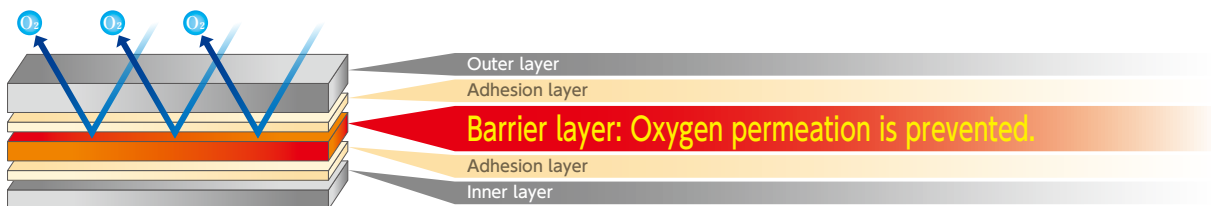
Type	Appearance	Main application	Performance
OXB		Solid pharmaceuticals Supplement	Oxygen permeability 0.5ml/m ² ·atm·24h ※25°C/40~60%RH Water vapor permeability 0.1g/m ² ·24h ※25°C/100%RH With 10 g silica gel

Product No.	Capacity (mL)	Total capacity (O. F. mL)	Bore (mm)	Size (Bottle body diameter (Φmm) × total height (mm))	Quantity
OXB-40	40	51.0	25.3	38.1×60.6	430
OXB-60	60	73.5	25.3	39.8×74.4	320
OXB-100	100	116.5	25.3	48.5×85.2	200

OxyBarrier™ is not included in our quality management system, ISO 9001.

Bottle structure

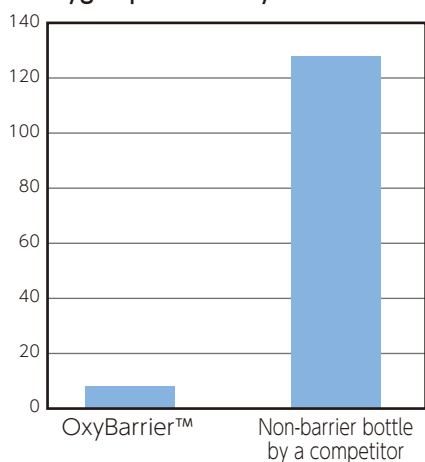
OxyBarrier™ has a special structure composed of five layers (three types).



Feature

- Prevents oxygen, which will cause pharmaceutical deterioration, from entering from the outside.
- Maintains the oxygen concentration in a bottle at a low level by a combination of an oxygen absorber for long-term storage of pharmaceuticals.
- Needs only a small oxygen absorber because of its high barrier properties.

■ Oxygen permeability ml/m²·atm·24h



	OxyBarrier™	Non-barrier bottle by a competitor
Oxygen permeability ml/m ² · atm · 24 h	0.5	129
Oxygen permeability of 100 mL bottle (mL/year)	2.5	645



* Study conditions: 25 °C, 40-60% RH

	OxyBarrier™	Non-barrier bottle by a competitor
Water vapor permeability g/m ² · 24 h	0.1	0.13
Moisture permeability of 100 mL bottle (g/year)	0.5	0.65

* Study conditions: 10 g silica gel was put in a bottle and the sealed bottle was stored at 25 °C and 100% RH for 28 days.

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

Product

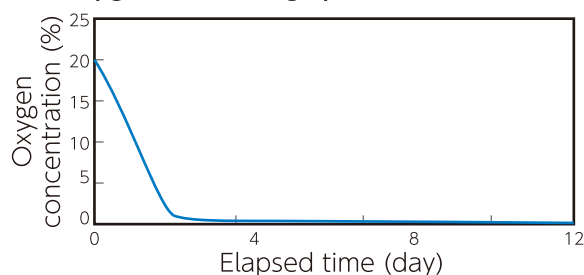
Type	Appearance	Main application	Feature	Oxygen absorption time
KD		Solid pharmaceuticals with low moisture content Medical devices	Compliance with FDA Registered in DMF	7 days (25°C)
CD			Compliance with FDA Registered in DMF Canister type	

Type	Product No.	Oxygen absorption capacity (mL)	Moisture absorption capacity (mL)	Size (mm)	Quantity		Handling time
					Loose (packets in a bag Xbags)	Roll (packets in a roll Xrolls)	
KD	KD-10S	10	0.07	50×20	4,000 (400×10)	-	Within 3 hours (25°C/50%RH)
	KD-10SR	10	0.07	50×20	-	4,000(2,000×2)	
	KD-20	20	0.15	62×26	4,000 (400×10)	-	
	KD-21	20	0.15	62×26	4,000 (100×40)	-	
	KD-20R	20	0.15	62×26	-	4,000 (2,000×2)	
	KD-400	400	3.0	135×100	250 (10×25)	-	
CD	CDA-0.55G	3	0.07	15φ×10	9,000 (1,500×6)	-	
	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)	-	
	CDA-2.8G	16	0.39	19.3φ×25.15	2,400 (400×6)	-	

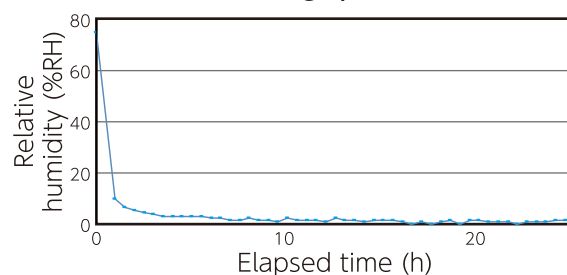
Feature

- 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

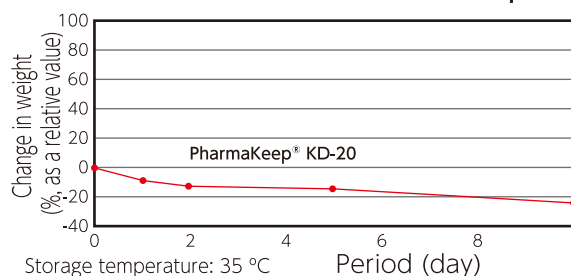


■ Moisture absorbing speed



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

■ Moisture transferred from a solid pharmaceutical product to PharmaKeep® KD-20



Storage temperature: 35 °C

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.

MoistureVanish™ Bottle with moisture absorbing function

Product

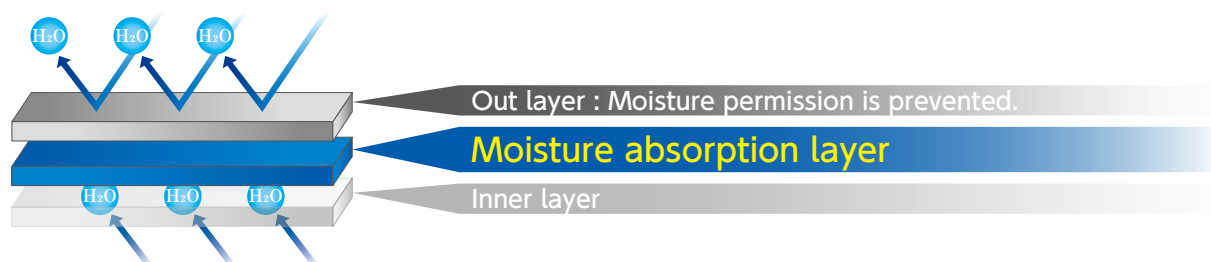
Type	Appearance	Main application	Moisture absorption capacity (g)
MVC		Solid pharmaceuticals	0.4 (40°C/90%RH)

Type	Capacity (mL)	Total capacity (O.F.mL)	Bore (mm)	Size (Bottle body diameter (Φ mm) × total height (mm))	Quantity
MVC-100	100	116.5	25.3	48.5×85.2	200

MoistureVanish™ is not included in our quality management system, ISO 9001.

Bottle structure

○ Moisture Vanish™ has a special structure composed of three layer.



Feature

- The moisture absorption function saves the time and effort of inserting desiccants.
- Maintains low humidity in the bottle to prevent hydrolysis of the API.

OXB Closure™ OxyBarrier's cap


Product

- The induction seal (high-frequency aluminum foil seal) put on the mouth of OxyBarrier prevents oxygen from entering from the fit between the bottle and the cap.

Type	Feature	Quantity
CL-32ST	Packing with induction seal	2,000

OXB Closure™ is not included in our quality management system, ISO 9001.

Product

Type	Appearance	Main application	Oxygen absorption time
ZPT-MBC		Liquid pharmaceuticals - Syringe - Ampule - API (Large type)	Within 2 days (Within 6 days for larger products than ZPT-500MBC)

Type	Product No.	Oxygen absorption capacity (mL)	Size (mm)	Quantity		Handling time (water activity value of product to be applied)
				Loose (packets in a bag × bags)	Roll (packets in a roll × rolls)	
ZPT-MBC	ZPT-20MBC	20	40×30	12,000 (400×30)	-	Loose: Within 4 hours Roll: ·1,000 or more sachets per hour (ZPT-20MBC to ZPT-300MBC) ·500 or more sachets per hour (ZPT-500MBC)
	ZPT-30MBC	30	40×35	8,000 (200×40)	8,000 (4,000×2)	
	ZPT-50MBC	50	40×40	6,000 (200×20)	6,000 (3,000×2)	
	ZPT-100MBC	100	45×40	3,000 (100×30)	3,000 (1,500×2)	
	ZPT-200MBC	200	45×55	1,500 (100×15)	1,500 (750×2)	
	ZPT-300MBC	300	60×60	1,500 (100×15)	1,500 (750×2)	
	ZPT-500MBC	500	60×70	1,000 (100×10)	1,000 (500×2)	
	ZPT-1000MBC	1,000	100×65	500 (50×10)	-	
	ZPT-2000MBC	2,000	100×90	250 (25×10)	-	
	ZPT-3000MBC	3,000	100×105	200 (20×10)	-	

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.

Point

AGELESS[®] 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 guarantee period is 6 or 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-EYE® Oxygen indicator

Product

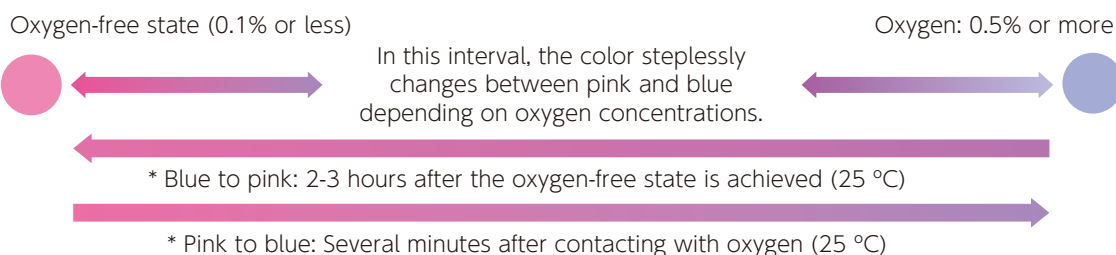
Type	Appearance	Type	Size	Quantity	Conditions of use
EYE-LS		Tablet type	41×33(mm)	6,000 (500 packets × 12 bags)	5~35°C, Aw0.10~0.99

Not Compliance with FDA

Feature

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

■ Image of color changing



■ Storage method and guarantee period of AGELESS EYE®

! AGELESS-EYE® products are delivered by room temperature courier service, and on arrival, immediately place them in a refrigerator and keep them at or below 15 °C with protection from light.

AGELESS-EYE®	Guarantee period
Tablet type	6 months after shipment, 15 °C

The oxygen concentration and time required for discoloration are rough standards 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 reused because the discoloration performance gradually decreases.
- After unpackaging of the outer bag of AGELESS-EYE®, enclose self-reacting AGELESS® Z or S 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 °C.

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 Oxygen absorbers

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 complete sealing using a sealer etc

If a package with an oxygen absorber is not completely sealed, it does not become oxygen-free.

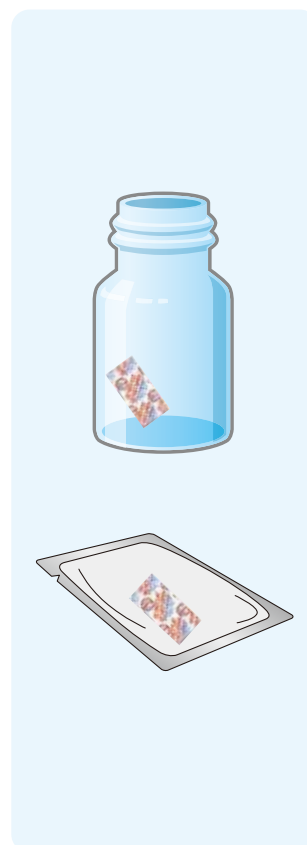
Completely seal the container with a sealer or another tool.

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.



mitsubishi gas chemical company, inc.

JAPAN (Head Office)

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