CAP + DESICCANT SILICA GEL

PHARMAGEUTIGAL PAGKAGING





WHAT IS SILICA GELP

Silica gel (SiO₂)_n is a polymer of silicon dioxide, synthetically made from sodium silicate. It is used in various fields as a desiccant (drying agent) for its dehydrating and extremely adsorbents properties. We can find silica gel in many kind of commercial products, from consumers electronics to pharmaceutical products. In this last case, it is often placed in a special container inside the cap. It is completely non-toxic according to the last regulations, non-stinging and it doesn't need any specific disposal process.



CHARACTERISTICS

Silica gel arises in a granular shape, with a variable particle size from few millimeters to few micron.

It can be in different colors: translucent white or yellow. It is vitreous and porous.



PROPERTIES

Silica gel preserves, safeguards and absorbs humidity for a better conservation of medicines' active ingredients and products in general.

Thanks to its specific chemical-physical properties of porosity, it activates an absorption process of water vapor. This exchange of physical matters makes the humidifying process very intense and rapid.

USES

Silica gel is used in every situation in which it is necessary to bring relative humidity down, and to safeguard products, goods and objects from deterioration. Fields of use are various and diversified: chemical, pharmaceutical, electronic, restoration works, museum preservation, transport, storage, gardening, domestic works and so on...







CAP

Aluminum caps with tamper evident are filled with a special canister in "Santoprene" able to include 0,6 gr. of brown silica gel.

The assembly "aluminum cap + silica gel" is packaged in special bags "double-barrier", with two years of guarantee.

Aluminum caps are available in three sizes (for neck 24 – 28 – 35) and suitable for the most common standard glass vials.



FINAL SUPPLY

ALUMINUM CAP WITH TAMPER EVIDENT

CANISTER WITH SILICA GEL

GLASS BOTTLE



This special final packaging is the best solution to safeguard medicine's active ingredients from moisture. In their original package, products keep intact for more than two years.



TECHNICAL DETAILS DESICCANT KIT

COMPONENTS	TECHNICAL DETAILS
AluminumCap/Ferrule	Aluminum gold cap/ferrule, externally varnished in white color, with 8 breaking points.
Container for dessicant Silica gel/retaining flange	Container for dessicant Silica gel/retaining flange in Santoprene "medical grade" EPDM 8281-75 + LDPE Riblene GP26 (60%-40%)
Little caps for container's closure	Cylindrical little cap in LDPE class Riblene GP26
Cardboard small disk for little cap's closure, with black ink notice "phaba do not ingest"	Cardboard small disk ø13 class RDM512-500. Black ink for printing out.
Dessicant Silica Gel "Brown" type	Micro porous silica gel apt to absorb water vapor, with chromatic indicator of depletion (turn color)
Containing bags for primary articles double-barrier	Aluminum heat-sealable bags, water vapor, gas and light resistant, apt to contain dessicant caps.

TECHNICAL SHEET N. U024.B00.ABA

PRODUCT

Aluminum screw cap 24x15 mm Roll-on Pilferproof type

MATERIALS

ALUMINUM

In compliance with regulation UNI EN 602 "Aluminum and aluminum alloys, chemical composition of semi-finished

products used for the production of objects dispatched to food contact"

Thickness: 0,21+/- 0,01

Physical condition: H14

Alloy: 3105 - 8011

Ultimate strength: 165-185 Mpa

VARNISHES

INTERNAL: Epoxy paint for foods

EXTERNAL: Polyester or vinyl varnish - polyester inks

ADJUVANT

Evanescent fluid fit for facilitate the deep-drawing, in compliance with FDA regulations

GARNISH

Possible graphics approved by Customer Tolerance of off-center graphics: 1 mm

USE CONDITIONS

ENTRANCE

In compliance with regulation: UNI 6144

APPLICATION

Closure with flat "pressing-mouth"

Re-beating and thread shaping by rotating roll

OPENING

Opening moment: 4 -9 cm/Kg

WAREHOUSE

Carton boxes of caps must be stored in a dry place, free from scents, protected from atmospheric agents, at a

temperature included between 5° and 40° C.

COMPLIANCE TO REGULATIONS

All used materials are suitable in accordance with the law DM of 21/03/73 (qualifying to food contact) and following updates, included DL 108 of 25/01/92, to the item 43, paragraph 4 of the law DL 22/97 (heavy metals), to the item 9 of directive 94/62/CE and attached F of the law DL 22/97 (essential requirements) and to the related FDA regulations.

User must be verify caps' compatibility with the product of contact, to guarantee the absence to chemical and organoleptic alterations.

BROWN SILICA GEL

Technical details Brown Silica Gel

ISSUE DATE: 06/07/2005 REV: 00

PRODUCT:

"BROWN SILICA GEL" is a dessicant silica gel with chromatic indicator of depletion. The basic raw material, used to create brown silica gel, is a micro porous gel apt to absorb water vapor.

1. APPLICATION:

The product is used to absorb water vapor.

Brown Silica gel changes its color during the absorption of water vapor. It passes from yellow (operative) to light-blue (finished).

2. CHARACTERISTICS:

- SHAPE: dessicant product is granular.
- GRAIN SIZE: 0,4- 1,5 mm (± 10 % max. out of range)
- REGENERATION: in the oven, at a temperature of 110 °C max. for the necessary time to get its yellow color back.
- COLOR OF BROWN SILICA GEL:

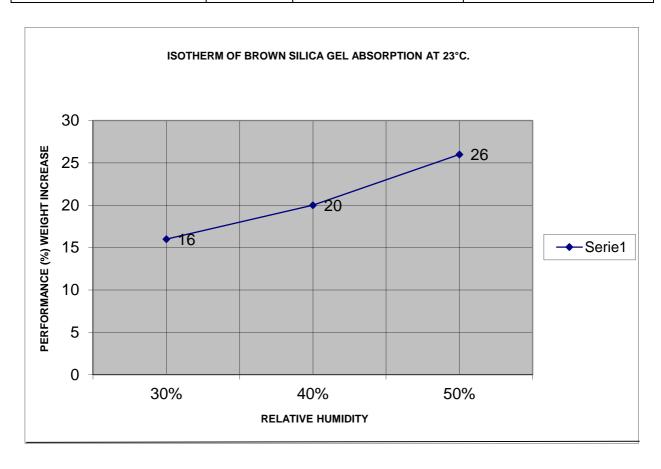
Color of brown silica gel operating / dry and	Color del brown silica gel finished / damp and				
indicative "pantone" references	indicative "pantone" references				
Color yellow with the following pantone ref:	Color light-blue with the following pantone				
3975 c, 397 c, or 398 c.	ref: 628 c, 629c, 630c, 631c				
NOTE: Dry product may contains darker crystals (brown) mixed with lighter ones (yellow).					

 STABILITY OF COLOR CHANGE: The product must not drop its functionality of color change if processed by the following ageing test:

Sample's exposure to UVB light								
Power lamps	of	UVB	Working sp range of UVB		Duration	Temperature	Result	
40W 295 nm to 340 nm (UVB) with peak at 313 nm			30°C	The product must not drop its functionality of color change				

3. TECHNICAL DETAILS:

PARAMETER	UNIT OF MEASURE	VALUE	METHOD
Residual humidity	(%)	Max 2 %	Infrared moisture balance 120°C 3 minuts
Specific weight	g/kg	700 – 800	BS 3482 .Part 10
рН		3,5-7	DIN 55473
Capability of water vapor's absorption	weight	(12 ±1)%	Climatic chamber at 20 % U.R. 23 °C
SEE ISOTHERM BROWN SILICA GEL ABSORPTION		(16 ±2)%	Climatic chamber at 30% di U.R 23°C
document: L-PH-BW –Isottherm_00		(20 ±2)%.	Climatic chamber at 40 % U.R. 23 °C
		(26±2)%	Climatic chamber at 50 % U.R. 23 °C
		(36 ±3)%.	Climatic chamber at 90 % U.R. 23 °C



DOUBLE-BARRIER BAGS

TECHNICAL DETAILS OF SUPPLY OF DOUBLE-BARRIER BAGS According to military standard MIL-PRF-131-J / MIL-PRF-131-K

COMPOSITION:

- 12 micron Leaf PETP
- adhesive
- 9 micron Aluminum Leaf
- adhesive
- 90 micron Leaf HD/HEXENLL black

TECHNICAL VALUES:

about 125 g/m² Weight according to EN 22286

(Tolerance +/- 10/15 % on nominal value)

Tension resistance MD 67 N/15 mm according to ISO 527

CD 64 N/15 mm according to ISO 527

Elongation MD 51% according to ISO 527

> CD 47 % according to ISO 527

160° C – 200° C Optimal conditions of soldering

Resistance to soldering's tear 56 N/15 mm at 180° C

Permeability to water vapor $< 0.05 \text{ g/m}^2/\text{d}$ according to DIN 53122

 -40° C to $+80^{\circ}$ C Resistance to temperature

REFERENCES

According TL 8135 - 0003 Type 1

According MIL - PRF - 131 K Class 1 (ex MIL – B – 131 J) Type 1

According DIN 55531 – 1 Type 1 Class 4

According NF H 00310