

DWK Life Sciences

WHEATON® DUALFUSION Vials

THE RIGHT PRODUCT,
INSIDE AND OUT



WHEATON®

DUALFUSION Vials

WHEATON DUALFUSION vials combine the best properties of glass, with the mechanical strength and the precision molding of plastic. The vials are engineered to protect pharmaceutical drugs and sample formulations that are prone to cause glass delamination and that are sensitive to oxidation via the permeation of atmospheric oxygen. Using a state-of-the-art Plasma Enhanced Chemical Vapor Deposition (PECVD) Technology, an organosilicate protective layer is fused with a silica-like (SiO_2 barrier) layer. These layers are fused to a Cyclic Olefin Polymer (COP) shell to form a robust covalently bonded material. The result is an inert surface that offers chemical resistance and unparalleled protection against container leachates and environmental stressors, such as oxygen.

Target Applications

WHEATON DUALFUSION vials do not experience delamination by the mechanism originating from ion exchange reactions or silicon network hydrolysis. While exhibiting low oxygen permeation rates similar to that of glass, these unique properties make DUALFUSION the vial of choice in the following packaging applications:

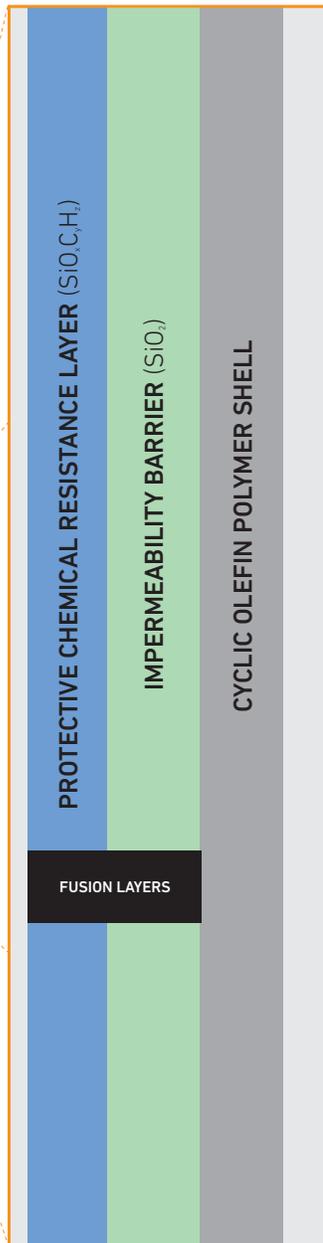
- Biologic drugs such as proteins, peptides, enzymes, DNA and RNA in complex formulations that are sensitive to leachates and oxidizing agents
- Low to high pH formulations that may interact with glass causing ion leaching and delamination
- High value, high potency and radioactive substances where container breakage is of great concern
- Cryogenic & O₂ Sensitive Storage

Performance Benefits

- **Glass-like Appearance:** Content visibility
- **Durability:** Shatter proof shell offers high value/hazardous content protection
- **Chemical Resistance:** Protective top layer offers hydrolysis protection, safeguards against pH shift and minimizes drug/container interactions
- **Inert & Pure:** A chemically inactive organosilicate protective top layer eliminates metal ion leachables found in glass
- **Impermeability:** Silica-like barrier blocks oxygen and other gas permeation assuring content integrity and shelf life
- **Workflow:** Nest & Tub configurations for automated fill & finish operations
- **Medical Grade Cleanliness & Sterility:** Leachables, particles and sterility meet the standards for parenteral packaging



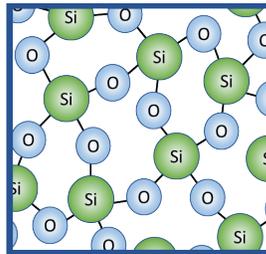
WHEATON® DUALFUSION Vials



COP Shell

- Superior durability than Type I borosilicate glass allows the vial to withstand higher compression force
- Ideally suited for high value and toxic content and high risk use environments
- Ability to withstand a wide range of temperatures (-196°C - 121°C)

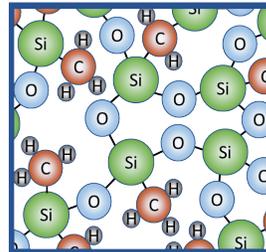
Barrier to Oxygen and Extractables



Fusion 1 (Barrier Layer)

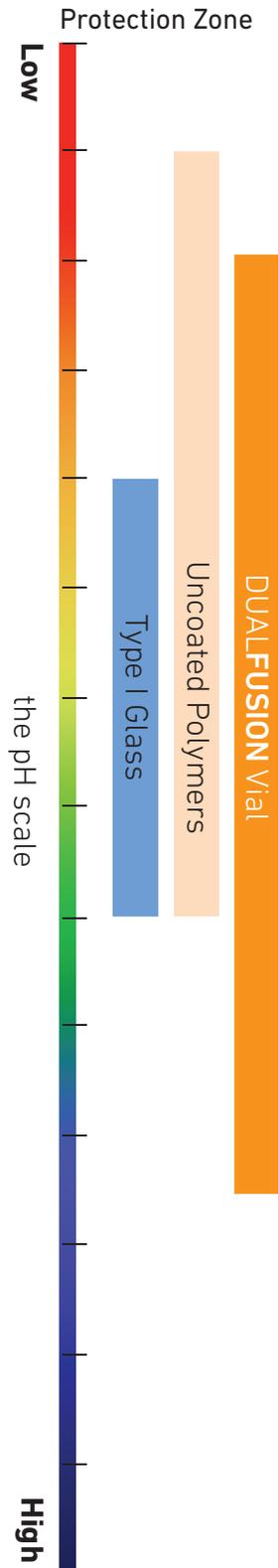
- A silica-like layer covalently bonded to the COP shell via an adhesion layer by PECVD Technology
- Blocks oxygen and other gas permeation from the atmosphere to the solution
- Prevents leachates from the COP shell and from label adhesives

Top Surface pH Protection



Fusion 2 (Protective Layer)

- An inert organosilicate protective layer that minimizes drug-container interaction
- A protective layer that safeguards against hydrolysis, pH shift and eliminates ion migration over a wide range of pH formulations (pH from 3 to 11)



Protection against Extractables and Leachables

Metal Ion Migration Due to Ion Exchange Reaction

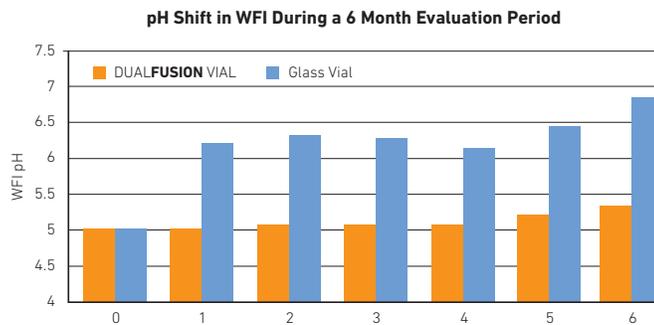
Extreme pH can affect the chemical durability of Type I glass surfaces resulting in delamination (ion migration or leaching of metal ions) and the appearance of unwanted particles in the pharmaceutical formulation. DUALFUSION vials completely eliminate alkali metal ion exchange and depletion of B and Na from the glass surface through its pure organosilicate protective layer applied to the COP shell.

Ion Leachate	Aluminum	Boron	Calcium	Iron
Type I borosilicate vials	450 ppb	580 ppb	290 ppb	50 ppb
DUALFUSION Vials	Not detected	Not detected	Not detected	Not detected

Acidic environment extraction performed with filled vials (pH 2.5) for 72 hours at 50°C and tested using ICP/OES. Detection limit for Al, B, Ca and Fe -5 ppb.

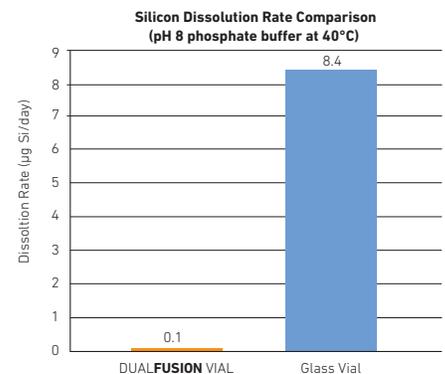
Minimizing the pH Shift in Water for Injection (WFI) Storage

The long-term storage of small volume water for injection (WFI) in glass may experience a shift in pH and increase the risk of delamination and non-compliance with pharmacopeia specifications. DUALFUSION vials filled with WFI (buffered to a pH of 5) and stored over a six month period demonstrated less pH shift compared to glass vials.

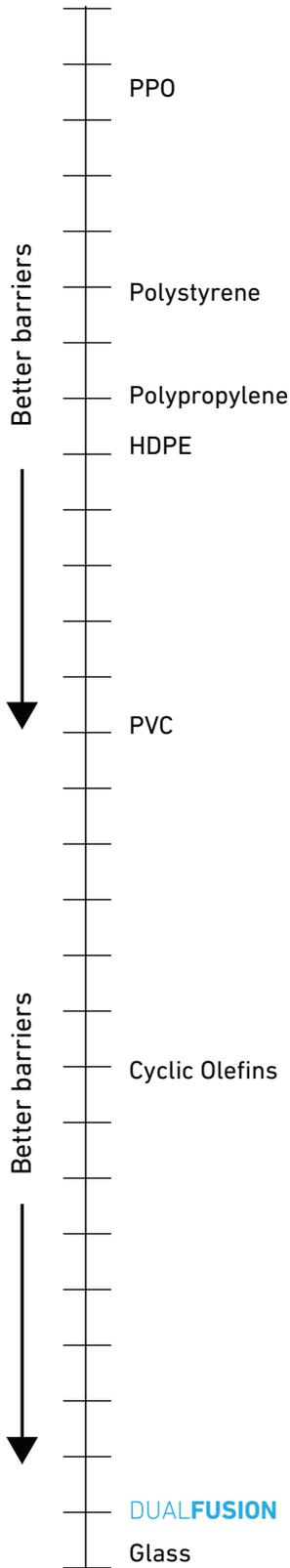


High pH: Silicon dissolution via Silicon-Oxygen (SiO) Network Hydrolysis

Phosphate buffers (pH 8.0) are commonly used in storage of different biologics substances and can result in silicon dissolution and leaching of metal ions from glass containers. DUALFUSION COP vials, with an organosilicate protective layer, demonstrate significantly lower silicate dissolution under accelerated conditions compared to Type I glass.



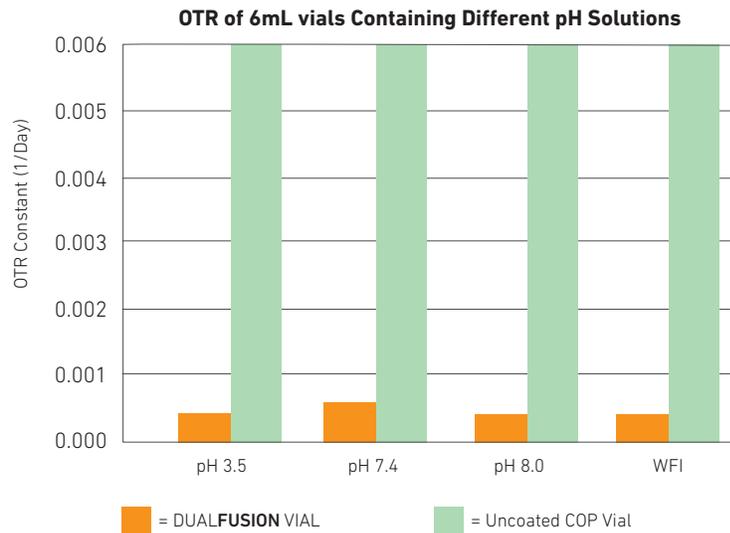
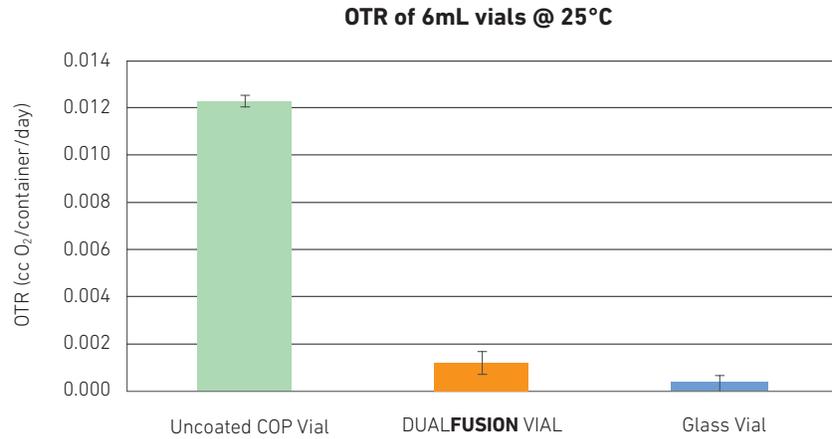
O₂ Permeability at 25°C



Protection from Oxygen Permeation

Superior Protection against Oxygen Permeation

Oxygen permeation, the rate at which a gas or vapor passes through a polymer, presents a real challenge to formulations that are sensitive to oxygen. These formulations may undergo oxidation or other degradation pathways that ultimately reduce drug efficacy during storage. DUALFUSION vials provide an excellent oxygen barrier and offer optimal protection from oxygen permeation and demonstrate much lower than other polymer vials.



WHEATON® DUALFUSION Vials

- Manufactured in a Class 7 Clean Room and E-Beam sterilized to meet USP<788> for low particulate levels and USP<85> for low endotoxin level for injectables
- Stand-alone nested tubs can be paired with Snap Cap and Aluminum Seal closure offerings
- DUALFUSION Vials available in stand-alone nested tubs or as part of a **COMPLETEPAK** offering
- **COMPLETEPAK** Configurations include closures and CoA

Cat. No.	Items Included	Pack Configuration	Qty/Pack
DUALFUSION Vials			
15-112-129	2mL Sterile COP Serum Vial	Vial Tub Qty 1	100
15-112-130	6mL Sterile COP Serum Vial	Vial Tub Qty 1	48
15-112-131	10mL Sterile COP Serum Vial	Vial Tub Qty 1	48
DUALFUSION—COMPLETEPAK Kits			
15-112-197	2mL COP Serum Vial Blue Snap Cap, 13mm Igloo Lyo Stopper, Sterile Tub	Vial Tub Qty 3 Cap Tub Qty 1	300
15-112-198	6mL COP Serum Vial Blue Snap Cap, 20mm Igloo Lyo Stopper, Sterile Tub	Vial Tub Qty 3 Cap Tub Qty 1	144
15-112-199	10mL COP Serum Vial Blue Snap Cap, 20mm Igloo Lyo Stopper, Sterile Tub	Vial Tub Qty 3 Cap Tub Qty 1	144
15-112-126	2mL Sterile COP Serum Vial Lyo Stopper Bag Blue Flip Off Seal Bag	Vial Tub Qty 2 Seal Qty 1 Stopper Qty 1	200
15-112-127	6mL Sterile COP Serum Vial Lyo Stopper Bag Blue Flip Off Seal Bag	Vial Tub Qty 4 Seal Qty 1 Stopper Qty 1	192
15-112-128	10mL Sterile COP Serum Vial Lyo Stopper Bag Blue Flip Off Seal Bag	Vial Tub Qty 4 Seal Qty 1 Stopper Qty 1	192

*DWK Life Sciences offers a variety of best in class rubber stoppers and aluminium seals that are compatible with the DUALFUSION vials. Contact your DWK Life Sciences representative for information on bulk pack options.



WHEATON® DualFusion Vials are manufactured by and sold under license from SiO2 Materials Science

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