

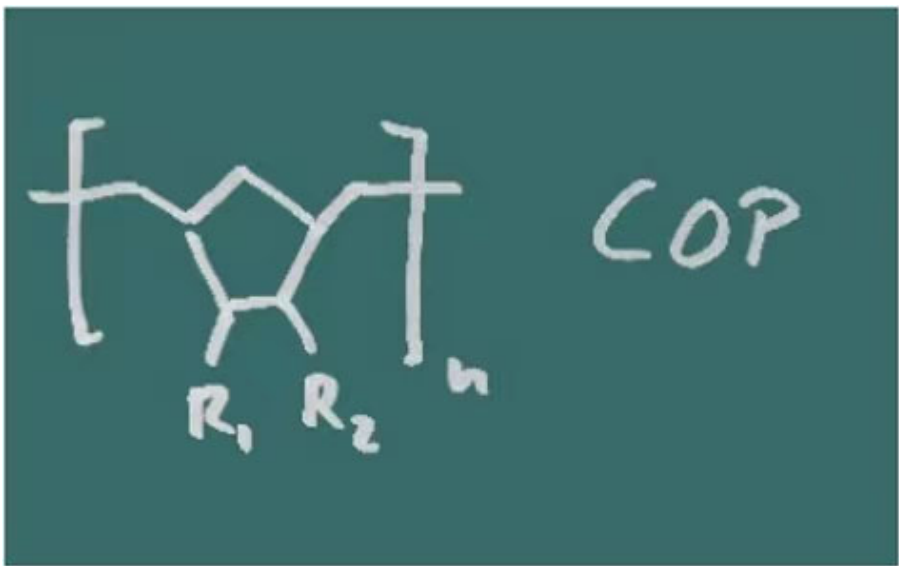
MEETING THE EVOLVING DEMANDS OF BIOPHARMACEUTICAL INDUSTRY: HIGH-PERFORMANCE IONIC CYCLIC OLEFIN POLYMERS (COP) FOR ADVANCED MEDICAL PACKAGING

Introduction

With the rapid development of the biopharmaceutical industry, there is an increasing demand for pharmaceutical packaging materials. COP (Cyclic Olefin Polymer), as a high-purity and highly transparent new polymer material, has gradually attracted attention in the industry. Compared to glass packaging materials, COP packaging materials have many advantages and are becoming the ideal choice in the fields of small molecule drugs and biopharmaceuticals.

What Is COP?

COP (Cyclic Olefin Polymer), is a non-crystalline, transparent high-polymer material with a cyclic olefin structure. It boasts advantages such as high transparency, excellent dimensional stability, low water absorption, superior gas tightness, chemical resistance, heat resistance, ease of processing and molding. It can replace glass materials and is applied in fields like optics and medical applications. Medical-grade COP, in particular, has stringent safety requirements.



Material Characteristics

- Amorphous Structure
- High Transparency
- Excellent Chemical Inertness and Biocompatibility
- High Purity, Free from Heavy Metal Ions
- Stable Mechanical Properties
- Resistance to Drugs at Various pH Levels, No Deformation
- Compatibility with Different Types of Medications
- Suitable for Repetitive Sterilization
- Resistant to Low Temperatures
- Suitable for Biopharmaceuticals

Application

COP packaging materials have the following main applications in pharmaceutical packaging:

1-Small Molecule Drug Packaging

COP materials can be widely used for packaging containers of various small molecule drugs, such as formulations, injections, etc. The high purity and inertness of COP materials ensure the safety and stability of small molecule drugs.

2-Biopharmaceutical Packaging

COP has extremely low protein adsorption and is ideal for packaging sensitive biopharmaceuticals such as vaccines, cell immunotherapies, protein drugs, etc. It helps maintain the activity of active drug ingredients.

3-Packaging Under Low Temperature Conditions

COP materials can withstand extremely low temperatures and are well-suited for storing and transporting drugs requiring low temperature conditions, such as mRNA vaccines.

4-Medical Aesthetics Packaging

COP materials are used for packaging injectable cosmetic medicines such as hyaluronic acid, botulinum toxin, etc.

5-Lab Consumables Packaging

COP can be used for packaging lab consumables such as microfluidic chips for microanalytic instruments, culture dishes, etc.

COP vs. Traditional Glass Packaging Materials

In the field of pharmaceutical packaging, the choice of material is of paramount importance as it directly impacts drug safety, transportation costs, and quality preservation. In this section, we will compare the performance differences between COP (Cyclic Olefin Polymer) packaging material and traditional glass packaging material. These two materials each have their advantages in pharmaceutical packaging but also exhibit significant differences. Let's delve into their comparison.

Properties	Glass	COP	COC	PP	PE	PP	PA	PET
Break resistance	-	+	+	+	+	+	++	++
O2-barrier	++	O	O	-	-	-	+	-
CO2-barrier	++	O	O	-	-	-	+	-
Water vapour barrier	++	+	+	++	O	++	O	+
Chemical resistance	+	+	+	+	+	+	O	+
pH-resistance	-	++	++	+	+	+	O	++
Extractables	+	++	++	+	+	+	+	O
Transparency	++	++	++	O	-	O	++	++
Steam sterilizable	++	+	+	+	-	+	+	-
Sterilisable by X-ray	-	+	+	+	+	+	+	O
Sterilisable by heat	++	-	-	-	-	-	-	-

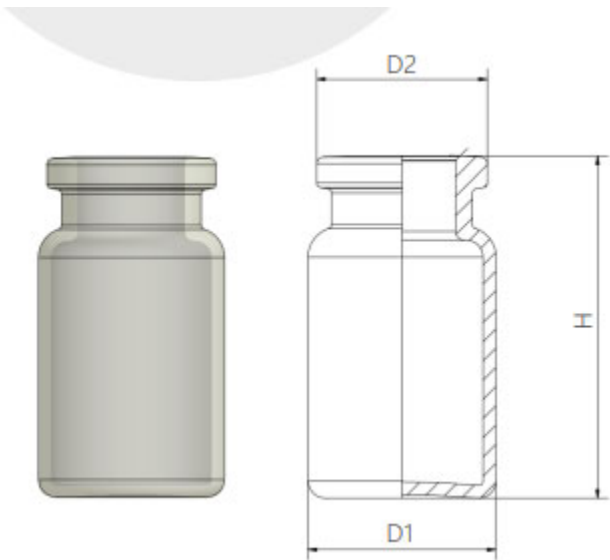
	Glass packaging	COP packaging
Safety	Risk of glass fragments	Will not shatter
Weight	Relatively heavy	Lightweight
Transportation cost	Relatively high	Lower
Chemical inertia	Mediocre	Extremely good
Protein absorption	More	Minimal
Temperature adaptability	Poor, not low temperature resistant	Good, low temperature resistant
Reusability	Not easy	Can be repeatedly sterilized

Tofflon COP Packaging Products

In the current pharmaceutical industry, competition is becoming increasingly fierce. Stringent regulatory standards and the evolving demands of end customers have given rise to the concept of "Tofflon Pharmaceutical Packaging," which aims to serve innovative, cost-effective drug packaging solutions.

A) COP Vials

COP Vials are a liquid medication packaging solution that combines the dual advantages of plastic and glass materials. Constructed with a monolayer structure of Cyclic Olefin Polymer (COP), this vial boasts an inert contact surface and chemical-physical properties that make it ideal for various applications, from biologicals and vaccines to small molecule formulations and radiopharmaceuticals. Its unique packaging design provides manufacturers of toxic or high value drugs with added security. The key dimensions of the COP Vials comply with ISO 8362 standards, but can also be tailored to meet specific customer requirements.



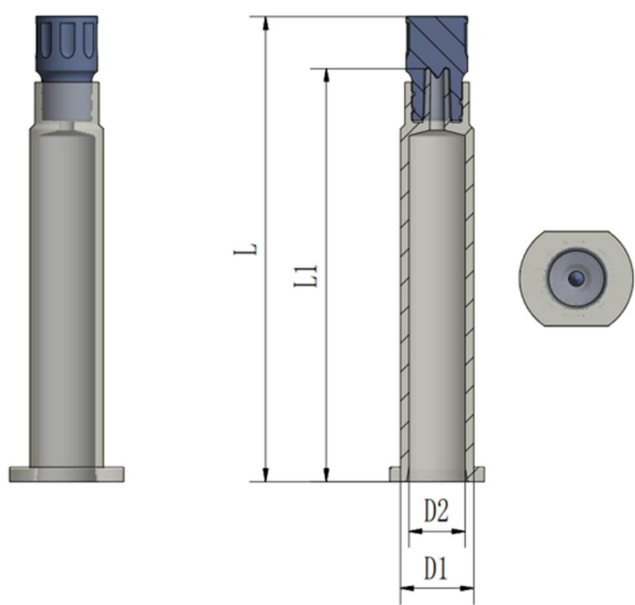
Key Features

- Customizable: Single-layer structure, specifications can be customized according to YBB00292005-2 or ISO8362 standards: 1ml-50ml.
- Drop Resistance: Made of COP material, it exhibits excellent drop resistance, remaining intact after a 15-meter drop.
- Comprehensive Performance: Combines all the excellent properties of both COP and glass materials while avoiding the drawbacks of glass.
- Dimensional Stability: Produced with imported equipment and molds using injection-blow molding technology, ensuring excellent dimensional and weight stability.
- Clean Environment: Produced in a 99% nitrogen-protected environment under Class A conditions, eliminating the need for washing and sterilization.
- Sealing Performance: Excellent sealing performance at both room temperature and low temperatures, suitable for demanding formulation processes.
- Biocompatibility: Meets the requirements for biocompatibility according to USP<87>, USP<88>, YBB, Chinese Pharmacopoeia, and GB16886.

Specification	Diameter (mm)	Height (mm)	Diameter of bottle mouth (mm)	Amount(PCS)
2R	16	35	13	100
3R	16	40	13	100
4R	22	45	13	100
6R	22	40	20	48
8R	24	45	20	48
10R	24	45	20	48
15R	30	60	20	48
20R	30	55	20	24
25R	30	65	20	24
30R	30	75	20	24
50R	40	73	20	16

B) COP Syringes

We offer a variety of volumes, ranging from small volumes (0.5 ml - 5 ml) to large volumes (10 ml, 20 ml, and 50 ml) in syringes. Our injection molding process, paired with our COP raw materials, allows for flexibility in design to create personalized solutions for specific pharmaceutical needs.



Key Features

- Various Specifications: Available in a range of sizes from 0.5ml to 50ml.
- Drop Resistance: Manufactured using COP material for excellent drop resistance, remaining intact even after a 15-meter drop.
- Comprehensive Performance: Combining all the excellent properties of COP and glass materials while avoiding the disadvantages of glass.
- Dimensional Stability: Produced using imported equipment and blow molding technology, ensuring exceptional size and weight stability.
- Clean Environment: Manufactured under a 99% nitrogen protective atmosphere in a clean room (C+A), providing a wash-free and sterilization-free packaging solution.
- Seal Performance: Equipped with a Luer cap and a film-coated plunger, ensuring excellent sealing performance at both room and low temperatures.
- Biocompatibility: Complies with the requirements for biocompatibility outlined in USP<87>, USP<88>, YBB, and GB16886.
- Extraction Test: Exhibits minimal extractables and releases no metal ions, demonstrating excellent drug compatibility.
- Luer Lock Connection: Compliant with ISO 80369-7 standards.

Packing Formats

Tofflon offers standardized Ready-to-Use (RTU) and TUB+NEST packaging solutions for both COP vials and syringes. The RTU format provides a ready-to-use, wash-free and sterilization-free packaging option through integrating containers, stoppers and caps. The TUB+NEST format separates containers and stoppers for added flexibility. These packaging formats enable efficient operations for pharmaceutical companies.

Specification	Inner diameter	Outer diameter	Length (mm)	Total length	Amount(PCS)
0.5ml	4.65	9.5	57	65	100
1ml Long	6.5	9.5	64.5	72.6	100
1ml	8.75	11.4	45.9	54	100
2.25ml	8.75	11.4	64.4	72.5	48
3ml	8.75	11.6	82.4	90.5	48
5ml	12.2	15	76.9	85	48
10ml	14.7	18	97.7	105.8	48
20ml	18.2	21.6	120.2	128.3	24
50ml	27.9	31.5	128.8	136.9	24

COP Technologies Outlook

COP materials can undergo various surface treatments to further enhance their functionality. For example, treatments such as hydrogenation, vapor-phase hydrogenation, and silanization can significantly improve their resistance to acidic and alkaline corrosion, reduce drug adsorption, and enhance their sliding properties. Tofflon is actively researching and applying these innovative COP technologies to develop high-performance COP packaging materials, aiming to provide greater value to customers and the industry. Additionally, Tofflon continues to develop innovative COP packaging products to meet the evolving needs of customers.

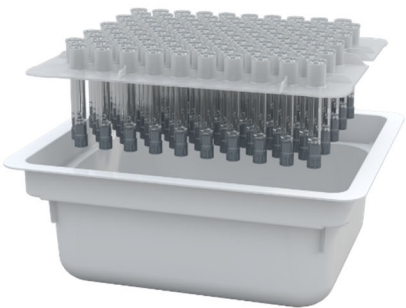
Conclusion

As an innovative pharmaceutical packaging material, COP has many unique advantages, and is especially suitable for new biopharmaceutical packaging. Tofflon has accumulated extensive experience and technical strength in this field, and is committed to providing safe and efficient COP packaging solutions for biopharmaceutical companies, in order to meet the needs of industry development. We firmly believe that COP material is definitely the future direction of pharmaceutical packaging. Tofflon will also continue to research and innovate, develop more revolutionary pharmaceutical packaging products based on COP, and make due contributions to the progress of the industry.



Sterilization Method

Sterilization is a critical step in pharmaceutical manufacturing to ensure drug safety. For COP packaging products, Tofflon provides ethylene oxide (EO) sterilization solutions. EO sterilization is a commonly used industrial sterilization method suitable for heat and moisture sensitive materials like COP. It can effectively kill microorganisms through EO gas while maintaining the integrity of packaging containers. Tofflon's EO sterilization procedure is optimized and validated to ensure robust sterilization efficacy for COP vials and syringes.



Method	COC/COP	Glass
Autoclave 121° C, 20 min ¹⁾	yes	yes
Gamma irradiation, 25 kGy ²⁾	yes	<u>no</u>
Electron radiation ²⁾	yes	<u>no</u>
X-Ray ²⁾	yes	<u>no</u>
Heat tunnel 280° C, 5 min	<u>no</u>	yes
Ethylene oxide	yes	yes

¹⁾ Minimal change in transparency and color, maintains mechanical properties
²⁾ Maintains mechanical properties, no influence on transparency, some color change