

DATA SHEET

COP Compatible: CDE: B20230000509 & DMF: NO.40745

COP/COC prefilled syringe assembly

Basic Parameters	Specification Table
Product Name	COP/COC Prefilled Syringe Assembly
Dimensions	1.0mL; 1.0mL Long; 2.25mL; 3.0mL
Product Specifications	1.0mL(ID 6.4mm, L 64.5mm); 1.0mL Long(ID 5.0mm, L 80mm); 2.25mL(ID 8.7mm, L 64.5mm) ; 3.0mL(ID 8.7mm, L 81.4mm)
Sterilization	EO Sterilization (Ready-to-use)
Temperature Resistance	-196°C~121°C
Gas Permeability (O ₂ , N ₂ , CO ₂)	Low
Water Vapor Permeability	Very Low
Transparency after Steam Sterilization and EO Sterilization	Excellent
Protein Adsorption	Very Low
Particle Shedding	None
pH Changes in the Drug	Stable (Almost No Change)
Strength	Good Toughness, Resistant to Damage

Testing Items	Testing Overview
Biocompatibility Test	Biocompatibility Testing according to YBB Standards (Systemic Toxicity, Skin Sensitization, Pyrogenicity, etc.)
Chemical Leaching Test	Chemical Leachability Testing according to USP <1660> and <1663> Standards.
Sealing Test	Pressure Retention Test under a -95 kPa Negative Pressure Environment.
Syringe Residual Volume Test	Testing according to GB15810-2019 regulations and standards, with residual liquid volume inside the syringe ≤ 0.07 mL.
Luer Cone Connector Test	Pre-filled Luer Lock connectors must undergo five tests: liquid leakage test, stress cracking test, load separation test, torque separation test, overload resistance test
Cap Removal Force Test	Pre-filled cap suspension force ≥ 22 N
Silicone Oil Uniformity and Quantity Test	According to YBB00112004-2015 standards, the silicone oil quantity in 1.0 mL to 2.25 mL syringes should be ≤ 0.7 mg and pass the uniformity test.
Insoluble Particulate Test	In accordance with YBB00272004-2015 regulations and standards, perform insoluble particulate testing on pre-filled syringes and their packaging materials.
Sterility and Endotoxin Test	In accordance with the relevant standards of the 2020 edition of the Pharmacopoeia of China, conduct sterility testing; According to YBB00112004-2015 standards, perform endotoxin testing.
Stability Test	The pre-filled syringes underwent environmental testing under three conditions: accelerated aging for 3 months, ambient temperature (25°C) for 12 months, and low temperature (2-8°C) for 12 months. After these exposures, the products successfully passed all performance validation tests, demonstrating their continued reliability and compliance with required standards.

Component Name	Material
Needle Tube	COP/COC
Luer Cap	Butyl Bromide

Accessory Name	Material
Rubber Stopper	Butyl Bromide
Booster	PP
Plunger	PC/PP

Packaging	Specification Table	Picture
Packaging Method	Nested Packaging (Without Accessory)	
Packaging Quantity	100 pcs/rack, 15 racks/case (1.0mL, 2.25mL); 100 pcs/rack, 16 racks/case (1.0mL Long, 3.0mL)	
Packaging Dimensions	260mm * 227.5mm * 97mm (1.0mL, 2.25mL); 260mm * 227.5mm * 122.5mm (1.0mL Long, 3.0mL)	

Product Range

COP/COC Prefilled Syringe Assembly (Rack Package)

Cat. No. (CN)	Cat. No. (EN)	Product Specifications	Cap Type	Connection Type	Packaging
205502	205602	COP, 1.0 mL Long	Soft Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case
205512	205612	COP, 1.0 mL	Soft Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
205522	205622	COP, 2.25 mL	Soft Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
205542	205642	COP, 3.0 mL	Soft Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case
225512	225612	COP, 1.0 mL	Soft Cap	Luer cone	100 pcs/rack, 15 racks/case, 1500 pcs/case
205503	205603	COP, 1.0 mL Long	Rigid Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case
205513	205613	COP, 1.0 mL	Rigid Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
205523	205623	COP, 2.25 mL	Rigid Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
205543	235643	COP, 3.0 mL	Rigid Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case
235502	235602	COC, 1.0 mL Long	Soft Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case
235512	235612	COC, 1.0 mL	Soft Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
235522	235622	COC, 2.25 mL	Soft Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
235542	235642	COC, 3.0 mL	Soft Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case
225012	225112	COC, 1.0 mL	Soft Cap	Luer cone	100 pcs/rack, 15 racks/case, 1500 pcs/case
235503	235603	COC, 1.0 mL Long	Rigid Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case
235513	235613	COC, 1.0 mL	Rigid Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
235523	235623	COC, 2.25 mL	Rigid Cap	Luer Lock	100 pcs/rack, 15 racks/case, 1500 pcs/case
235543	235643	COC, 3.0 mL	Rigid Cap	Luer Lock	100 pcs/rack, 16 racks/case, 1600 pcs/case

Prefilled Syringe Accessory (Non-sterile, Double Bag Package)

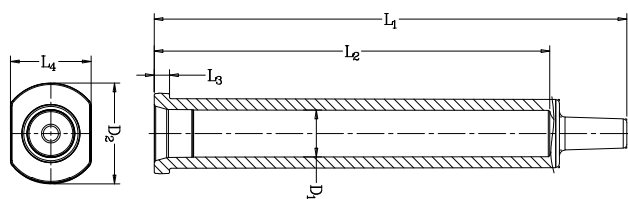
Cat. No. (CN)	Cat. No. (EN)	Product Specifications	Packaging
205571	205671	Plunger Rod, Suitable for 1.0 mL Long COP/COC Prefilled Syringe	3500 pcs/pack, 1 pack/case, 3500 pcs/case
205591	205691	Plunger Rod, Suitable for 1.0 mL COP/COC Prefilled Syringe	5000 pcs/pack, 1 pack/case, 5000 pcs/case
205581	205681	Plunger Rod, Suitable for 2.25 mL COP/COC Prefilled Syringe	5000 pcs/pack, 1 pack/case, 5000 pcs/case
205551	205651	Plunger Rod, Suitable for 3.0 mL COP/COC Prefilled Syringe	3500 pcs/pack, 1 pack/case, 3500 pcs/case
205572	205672	Backstop, Suitable for 1.0 mL Long COP/COC Prefilled Syringe	3500 pcs/pack, 1 pack/case, 3500 pcs/case
205592	205692	Backstop, Suitable for 1.0 mL COP/COC Prefilled Syringe	10000 pcs/pack, 1 pack/case, 10000 pcs/case
205582	205682	Backstop, Suitable for 2.25 mL and 3.0 mL COP/COC Prefilled Syringe	10000 pcs/pack, 1 pack/case, 10000 pcs/case

Product Range

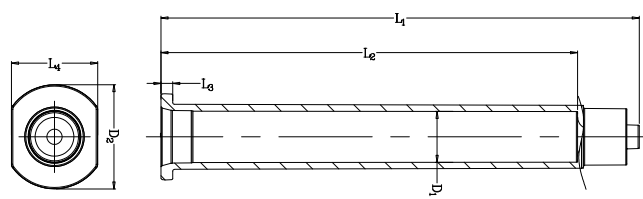
Combination Kit

Cat. No. (EN)	Product Specifications	Cap Type	Connection Type	Packaging
Y205602	COP, 1.0 mL Long	Soft Cap	Luer Lock	Prefilled Syringe: 100 pcs/rack; Plunger Rod: 100 pcs/bag; Backstop: 100 pcs/bag; Plunger Stopper: 110 pcs/bag; 100 sets/case
Y205612	COP, 1.0 mL	Soft Cap	Luer Lock	
Y205622	COP, 2.25 mL	Soft Cap	Luer Lock	
Y205642	COP, 3.0 mL	Soft Cap	Luer Lock	
Y225612	COP, 1.0 mL	Soft Cap	Luer cone	
Y205603	COP, 1.0 mL Long	Rigid Cap	Luer Lock	
Y205613	COP, 1.0 mL	Rigid Cap	Luer Lock	
Y205623	COP, 2.25 mL	Rigid Cap	Luer Lock	
Y205643	COP, 3.0 mL	Rigid Cap	Luer Lock	
Y235602	COC, 1.0 mL Long	Soft Cap	Luer Lock	
Y235612	COC, 1.0 mL	Soft Cap	Luer Lock	
Y235622	COC, 2.25 mL	Soft Cap	Luer Lock	
Y235642	COC, 3.0 mL	Soft Cap	Luer Lock	
Y225112	COC, 1.0 mL	Soft Cap	Luer cone	
Y235603	COC, 1.0 mL Long	Rigid Cap	Luer Lock	
Y235613	COC, 1.0 mL	Rigid Cap	Luer Lock	
Y235623	COC, 2.25 mL	Rigid Cap	Luer Lock	
Y235643	COC, 3.0 mL	Rigid Cap	Luer Lock	

Technical Drawing



Luer cone



Luer Lock

	L1	L2	L3	L4	D1	D2
1.0 mL Luer Lock	64.5	54.0	2.1	11.0	6.4	13.8
1.0mL Long Luer Lock	80.0	69.8	2.3	11.0	5.0	13.8
2.25 mL Luer Lock	64.5	54.0	2.1	14.7	8.7	17.8
3.0 mL Luer Lock	81.4	70.9	2.1	14.7	8.7	17.8
1.0mL Luer cone	64.5	54.0	2.1	11.0	6.4	13.8