

DATA SHEET

USA DMF No. 42439

Cartridge Assembly for Pen-injectors

Basic Parameters	Specification Table
Product Name	NEST Cartridge Assembly for Pen-injectors
Dimensions	3.0mL (Φ11.6×64.1mm); 2.0mL (Φ11.6×47.8mm); 1.5mL (Φ11.6×44.3mm)
Product Specifications	3.0mL; 2.0mL; 1.5mL
Sterilization	Steam sterilized (SAL = 10 ⁻⁶), ready to use

Packaging	Specification Table	Picture
Packaging Method	Rack Package (Without Accessory)	
Packaging Quantity	100 pcs/rack, 15 racks/case, 1500 pcs/case	
Packaging Dimensions	260.7mm * 220.5mm * 88.2mm	

Testing Items	Testing Overview
Biocompatibility Test of Cartridge Assemblies	Biocompatibility tests per USP: skin irritation, sensitization, in vitro hemolysis
Physicochemical Purity Test of Cartridge Assemblies	Compatibility studies performed per USP <1663>/<1664>; insoluble particulate matter tested per YBB00272004-2015.
Heat Resistance and Internal Stress Test of Glass Barrel	Determined according to the relevant standards of YBB00132004-2015.
Water Resistance Test of Glass Barrel	Determined according to the relevant standards of YBB00132004-2015, the water resistance of particles meets Level 1 at 121°C; the internal surface water resistance meets HC1 level.
Silicone Uniformity and Silicone Quantity Test	According to the relevant standards of YBB00112004-2015, the silicone oil amount in the 3mL cartridge is ≤1mg, and it passes the uniformity test.
Aluminum Cap Fit and Coating Adhesion Test	The aluminum cap passes the compatibility test with the borosilicate glass sleeve (YBB00142004-2015). The aluminum cap coating passes the corrosion test with ethanol and isopropanol solutions.
Rubber Stopper Adhesion and Coring Test	When the gasket shifts within the aluminum cap, the separation force is ≥1.0N; in the simulated puncture test, using microscopic observation, the total number of particles from 50 punctures is ≤3.
Seal Integrity Test	Through the pressure-holding test under a -95 kPa vacuum environment.
Sterility and Endotoxin-Free Test	According to the 2020 edition of the Chinese Pharmacopoeia, the sterility test is performed by direct immersion method, and the endotoxin test is performed using the colorimetric method.

Component Name	Material
Bottle Body	Borosilicate Glass
Bottle Cap	Aluminum Cap
Gasket	Polyisoprene, Bromobutyl Rubber

Accessory Name	Material
Rubber Stopper	Butyl Bromide

Product Range

Cartridge Assembly for Pen-injectors (Non-Pyrogenic, Non-Toxic, Sterile, Rack Package, 100pcs/rack, 15 racks/case)

Cat. No. (CN)	Cat. No. (EN)	Product Description	Gasket
217231	217232	NCPR-01, Pre-crimped 3.0 mL Cartridge	Double-layer
217101/ 217201	217202	NCPR-05, Pre-crimped 3.0 mL Cartridge	Double-layer
217161/ 217261	217262	NCPR-05, Pre-crimped 3.0 mL Cartridge	Mono-layer
217163/ 217263	217264	NCPR-05, Pre-crimped 3.0 mL Amber Cartridge	Mono-layer
216101/ 216201	216202	NCPR-04, Pre-crimped 2.0 mL Cartridge	Double-layer
215101/ 215201	215202	NCPR-07, Pre-crimped 1.5 mL Cartridge	Double-layer

Note: Long stoppers or short stoppers are optional.

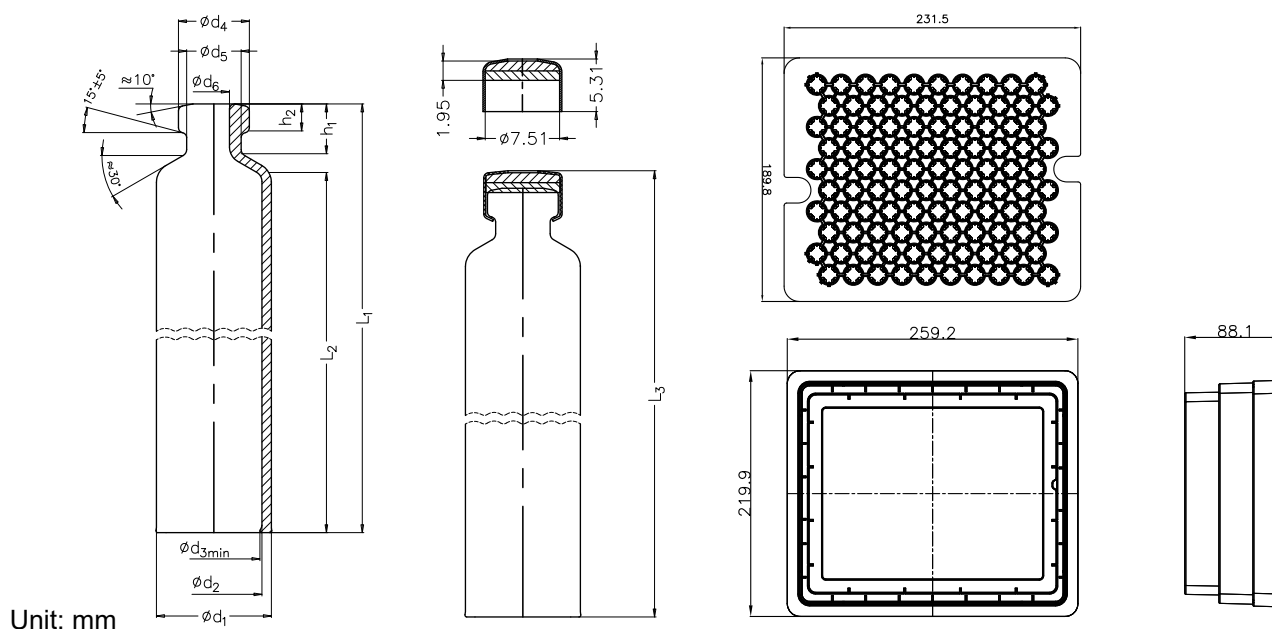
Accessories Series-Cartridge Assembly for Pen-injectors - Stopper (Double Bag Package)

Cat. No. (EN)	Product Description	Type	Product Packaging
217962	Short Stopper, Red, Sterile, Ready to use	Premium	7000 pcs/pack, 7000 pcs/case
217982	Short Stopper, Red, Sterile, Ready to use	Economic	5000 pcs/pack, 5000 pcs/case
217922	Long Stopper, Grey, Sterile, Ready to use	Economic	5000 pcs/pack, 5000 pcs/case
217952	Short Stopper, Red, Sterile, Ready to use	Premium	100 pcs/pack, 1500 pcs/case
217972	Short Stopper, Red, Sterile, Ready to use	Economic	100 pcs/pack, 1500 pcs/case
217912	Long Stopper, Grey, Sterile, Ready to use	Economic	100 pcs/pack, 1500 pcs/case

Kit Series (Non-Pyrogenic, Non-Toxic, Ready to use)

Cat. No. (EN)	Product Description	Gasket	Product Packaging
217252	NCPR-01, Pre-crimped 3.0 mL Cartridge, Red Short Stopper	Double-layer	Cartridge: Rack Package, 100 pcs/rack; Stopper: Double Bag Package, 100 pcs/pack; 500 sets/case
217212	NCPR-05, Pre-crimped 3.0 mL Cartridge, Red Short Stopper	Double-layer	
217112	NCPR-05, Pre-crimped 3.0 mL Cartridge, Grey Long Stopper	Double-layer	
217272	NCPR-05, Pre-crimped 3.0 mL Cartridge, Red Short Stopper	Mono-layer	
217172	NCPR-05, Pre-crimped 3.0 mL Cartridge, Grey Long Stopper	Mono-layer	

Technical Drawing



Volume (mL)	ϕd_1	ϕd_2	ϕd_{3min}	ϕd_4	ϕd_5	ϕd_6	h_1	h_2	L_1	L_2	L_3
1.5	11.6	9.65	9.35	7.15	5.5	3.15	5.0	2.9	42.5	35.7	44.3
2.0	11.6	9.65	9.35	7.15	5.5	3.15	5.0	2.9	46.0	39.2	47.8
3.0	11.6	9.65	9.35	7.15	5.5	3.15	5.0	2.9	62.3	55.5	64.1