

DATA SHEET

CDE: B20230000050 & DMF: NO.38260

Prefilled Nasal Spray Assembly



Basic Parameters	Specification Table
Product Name	Prefilled nasal spray assembly
Dimensions	OD:6.85mm; L:68.0mm (with cap)
Product Weight	3.4g
Product Specifications	0.5mL
Sterilization	EO Sterilization (Ready-to-use)
Spray Particles	10-70 μ m (medium water), the actual range needs to be determined based on the liquid density
Precise Dosage	0.14 mL dose limiter, ensuring stable and uniform dosing

Component Name	Material
Glass Syringe	Borosilicate Glass
Nasal Atomizer	PC
Spray Nozzle	PC
Nasal Spray Cap	Polyisoprene Rubber

Accessory Name	Material
Limiter	PP
Plunger	PP
Rubber Stopper	Bromobutyl

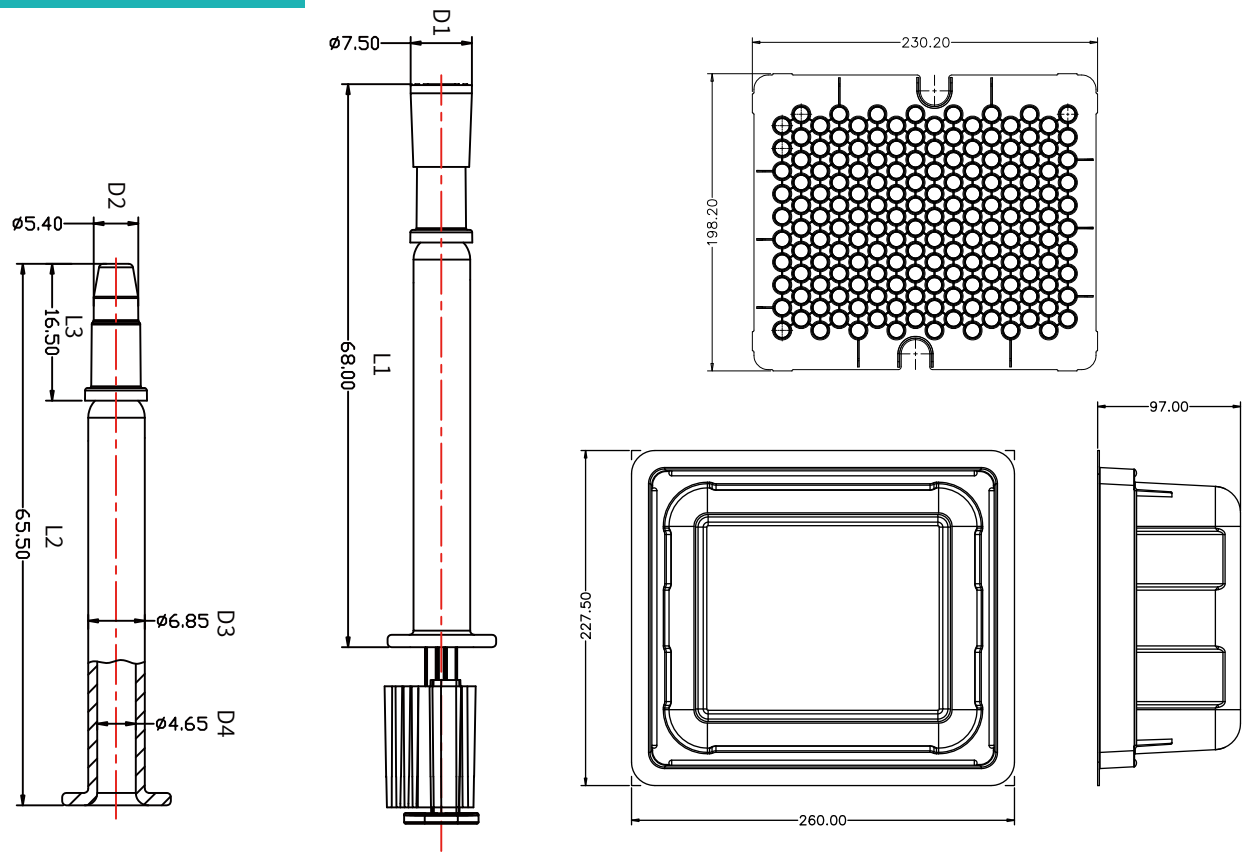
Testing Items	Testing Overview
Biocompatibility Testing	Biocompatibility Testing according to YBB standards (including acute systemic toxicity, in vitro cytotoxicity, skin sensitization, pyrogen, hemolysis, intracutaneous irritation, primary skin irritation, etc.)
Chemical Leachate Testing	Chemical Leachate Testing according to USP <1660> and <1663> standards.
Atomization Performance Testing	Quickly push the syringe with force, and the ejected liquid should be in a mist form. The entire process should be free of blockage, tilting, or straight-line jetting.
Atomization Particle Testing	Add an amount of injectable water equal to half the syringe's capacity, and perform the test using the relevant instruments, DV10:22±4µm, DV50:41±6µm, DV90:75±10µm
Atomization Analysis in SP Mode	Add an amount of injectable water equal to half the syringe's capacity. Use the Spray View analyzer from Proveris (USA) to analyze the two-dimensional spray image through laser diffraction. Perform the test in Spray Pattern mode, with the Ovality value between 1 and 1.7.
Atomization Analysis in PG Mode	Add an amount of injectable water equal to half the syringe's capacity. Use the Spray View analyzer from Proveris (USA) to analyze the two-dimensional spray image through laser diffraction. Perform the test in Plume Geometry mode, with the Angle required to be ≥35°.
Sealing Performance Testing	Fill the glass syringe with injectable water equal to half its capacity, and maintain pressure at -88 kPa for 30 minutes. There should be no leakage at the contact point between the glass syringe and the piston, as well as at the spray nozzle.
Silicone Oil Content Testing	Use a silicone solvent to extract silicone oil from the syringe, with an average silicone oil content of ≤ 0.6 mg per syringe.
Nozzle Adhesion Strength Testing	Use a tensile tester to perform the pull force test at a speed of 200 N/mm.min. The separation force between the syringe and the nasal spray device should be ≥ 100 N.
Sliding Performance Testing	Perform the test according to the YBB00112004-2015 standard. The starting force for piston sliding should be < 10 N, and the maintaining force should be < 5 N.
Body Integrity Testing	Perform the test according to the YBB00112004-2015 standard. There should be no leakage at the connections between the spray nozzle and atomizer, the spray head and syringe, or the piston and syringe barrel.
Syringe Residual Volume Testing	According to GB 5810-2019 standard, when the plunger is fully pushed to the bottom of the glass syringe, the volume of liquid remaining inside the syringe should be ≤ 0.07 mL.
Self-destruction Testing	According to the YY 0573.4-2010 standard, the syringe is not reusable after use. After the syringe is used, manually pull the plunger backward. The piston should separate from the plunger and remain inside the glass barrel.
Cap Removal Force Testing	Use a pharmaceutical packaging material peel force tester. The cap removal force should be between 4 and 30 N.
Self-stability Testing	The prefilled nasal spray assembly, after being subjected to three different environmental conditions—accelerated aging for 3 months, room temperature (25°C) for 3 months, and low temperature (2-8°C) for 3 months—should still pass all performance validation tests.

Product Range

Cat. No. (CN)	Cat. No. (EN)	Product Description
205001	205101	0.5mL, Sterile

Packaging	Specification Table	Picture
Packaging Method	Nested Packaging (Without Accessory)	
Packaging Quantity	160 pcs/pack, 15 packs/case	
Packaging Weight	805.3g/pack	
Packaging Dimensions	260mm * 227.5mm * 97mm	

Technical Drawing



	L1	D1	L2	L3	D2	D3	L2
0.5mL	68.00	φ7.50	65.50	16.50	φ5.40	φ6.85	φ4.65