

DATA SHEET

CDE:B20250000729

Prefilled Automatic Pen Injector Assembly

Specification	Technical Data Sheet
Product Name	Prefilled Automatic Pen Injector Assembly
Size	168.0*24.2mm
Product Weight	Standard: 47.7g; High-Viscosity: 48.4g
Injection Dose Range	Standard: 0.4-2.25mL; High-Viscosity: 0.4-1.8mL
Method of Use	Two-step process
Audible Feedback	When start and finish injection, there exits audible alert
Window	Easy to identify the state of use
Injection Time	Standard $\leq 10s$; High-Viscosity $\leq 20s$ (Determined by the viscosity of the reagent solution)
Needle diameter	29 G TW or Larger
Injection Depth	6mm $\pm$ 2mm
Needle safety distance	$\geq 4.5mm$
Triggering Force	5-15N
Safety lock force	$\geq 60N$
Compatible with 1.0 mL Long Prefilled Syringe	Length: 65.4mm, Outside Diameter: 10.85mm, Inside Diameter: 8.65mm
Storage Temperature	Without drug solution: Store at room temperature. With drug solution: Store according to the storage temperature requirements of the drug solution.
Shelf Life	5 years
Batch No.	LOT is shown on outer box label

ISO 11608-1 Test Items	Test Content
Cool Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 4 h in the atmosphere(Temperature: $5\pm 3^{\circ}\text{C}$)
Standard Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 4 h in the atmosphere(Temperature: $23\pm 5^{\circ}\text{C}$; Humidity: $50\pm 25\%\text{RH}$)
Warm Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 4 h in the atmosphere(Temperature: $40\pm 2^{\circ}\text{C}$; Humidity: $50\pm 10\%\text{RH}$)
Free Fall Reliability Testing	Falling down to the steel plate from height of one meter
Dry-Heat Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 96 h in the atmosphere(Temperature: $70\pm 2^{\circ}\text{C}$; Humidity: $50\pm 10\%\text{RH}$)
Freezing Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 96 h in the atmosphere(Temperature: $-40\pm 3^{\circ}\text{C}$)
Vibration Atmosphere Reliability Testing	Vibrate the NIS with its container and needle in each of the three axes in accordance with Table 8 and IEC 60068-2-6:2007,Figure 1
Transport Testing	Conduct transportation verification using the final packaging of the product.
Functional Stability Testing	Being placed in a test chamber to precondition for 5 months in the atmosphere(Temperature: $60\pm 2^{\circ}\text{C}$; Humidity: $55\pm 25\%\text{RH}$)
Dose Delivery Efficiency Testing	$\geq 96.5\%$

Component Name	Material
Pen Cap	PC
Housing	PC
Needle Guard	PC
Spring	Stainless steel
Syringe Barrel Holder	PC
Plunger Sleeve	PC
Plunge	PC

Packaging	Technical Data Sheet
Product Packing	Bag Package
Individual Case load	1 set/pack

Technical Drawing

