Your best choice for laboratory and medical consumables

Customizable Pen Injector & Pen Injector Assembly

NEST®
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Customizable Pen Injector & Pen Injector Assembly

In the pen injector product area, NEST has introduced customizable pen injectors as well as the more convenient and safer pen injector assembly (in the future, NEST will introduce a full range of cartridge bottles). These products are widely used for the administration of drugs such as insulin, follicular hormone, growth hormone, antibiotics, etc., making it easy and safe for patients to inject their medications.

FIRST CASE IN CHINA! NEST lands another FDA 510K certification for disposable pen injector!

Disposable pen injector NO.: K240961

Reusable pen injector NO.: K240774

Product Name	Product Specifications	Minimum Dosage	Major Numbered Scale	Usual Unit in Use	Intended Use
Disposable Pen Injector Assembly	80 increments, 3ml cartridge	0.01mL	0-2-...-80	U	Mix of insulin aspart and insulin degludec.
	74 increments, 3ml cartridge	0.01mL	0-0.25-0.5-1.0 (or 0.5/2.0mg maximum)	mg	Semaglutide (various dosage: 0.68mg/ml，1.34mg/ml，2.68mg/ml) for diabetes.
	60 increments, 3ml cartridge	0.01mL	0-2...-60 even number	U	Insulin aspart; insulin glargine.
	50 increments, 3ml cartridge	0.01mL	0-0.6-1.2-1.8-2.4-3.0	mg	Liraglutide injection.
	36 increments, 3ml cartridge	0.0208mL	0-12.5-25...-450	IU	Follicle-stimulating hormone (FSH) injection.
	37 increments, 3ml cartridge	0.01mL	0-0.25-0.5	mg	Semaglutide (1.34mg/mL, 0.5mg)
	Fixed dose, 8 increments 1.5ml cartridge	0.08mL	0-Inject	None	Human parathyroid hormone(PTH)-related peptide analogs for the treatment of high-risk osteoporosis in menopausal women.
Reusable Pen Injector	60 increments, 3ml cartridge	0.01mL	0-1-2...-60 even number	U	Insulin aspart.
	60 increments, 3ml cartridge	0.0075mL	0-2...-60 even number	U	Human growth hormone (hGH)
	80 increments, 3ml cartridge	0.01mL	0-2-...-80	U	Insulin aspart/degludec mix; insulin glargine, insulin glulisine.
	75 increments, 3ml cartridge	0.01mL	0-1.0; 0-1.7; 0-2.4	mg	Semaglutide for weight loss, weight control.
Fixed-dose Pen Injector	Fixed dose, 80μL, 3 ml cartridge	0.08mL	0-Inject	None	Human parathyroid hormone(PTH)-related peptide analogs for the treatment of high-risk osteoporosis in menopausal women.

1 Comprehensive services

Founded in 2009, Wuxi Nest Biotechnology Co., Ltd. (hereinafter referred to as “Nest”) is dedicated to research, development, and manufacturing of high-quality life sciences products.

Based on years of continuous investment in R&D and improvement of business chain, NEST's service scope covers the whole line of independent control from product design, process design, mold design and manufacturing, injection molding, surface treatment, irradiation sterilization, etc., and has the integration service capability of automation and flexibilization characteristics, which has formed the technological characteristics of independent innovation and rapid realization of products within the industry (including the business of cassette bottles).

The company now has 6800 m^2 of 100,000 class clean room, 2700 disposable of 10,000 class clean room, reaching the international advanced level; at present, it has obtained ISO 9001, ISO 13485, ISO 11137, FDA, CE certification and medical device production license, and standardized production with reference to the GMP quality management standards, and it has passed the third-party's regular monitoring, which can ensure that the product manufacturing process and packaging process meet the standardized requirements.

NEST products are mainly: disposable laboratory consumables, pharmaceutical packages and medical devices.

1.1 Full industry chain structure, emphasizing the advantages of mold design, injection blow molding, packaging and sterilization.

Among them, molding tool R&D is one of the core technologies of the life science consumables . We have strong mold design and manufacturing capabilities, with more than 50 professional mold R&D team to meet customer needs in the long term. The company has the ability to design and develop molds can effectively shorten the mold development cycle.
Secondly, the company adopts the internationally advanced automatic high-speed injection molding machine, together with the industry's advanced hot runner injection system, can realize the design and manufacture of multi-cavity, thin-walled, transparent and high-precision products.

NEST has the internationally advanced fully automated electronic irradiation equipment RhodotronTT200, the company can ensure that the production, supply and marketing within a distance of 100 meters to complete the closed-loop, reduce the risk of contamination of the products generated by the long distance, further improve the efficiency of the production and marketing and to protect the quality of the products.

1.2 Advantages of polymer materials exploration

We specialize in the research of polymer materials, master the modification processing technology. The familiarity with PP, PC, PBT and other materials performance and product application has accumulated a wealth of experimental experience. At the same time, our material engineers are still actively exploring the new direction of environmental protection grade plastics, medical grade plastics and special functional polymer materials. In the early stage of product development, we try to select environmentally friendly materials as the first priority.

1.3 Global Layout

NEST strives to render superior products and services to customers all over the world. We have established subsidiaries in the United States, Holland, United Arab Emirates and Japan to develop and expand our brand in overseas market. The subsidiary in the United States has developed businesses in overseas market for over ten years; a new warehouse acquired by Nest in West America has been completed and is now providing foreign customers with integrated services covering warehousing, logistics and distribution.

A number of products of Nest are sold to more than 70 countries such as the United States, Germany, French, Japan, South Korea and India, and end users of our products include prestigious universities at home and abroad and life science institutes. Nest has rendered services to many internationally or domestically influential corporations and organizations such as WHO, Thomas Scientific, Eurofins, GenScript Biotech Corporation and Wuxi Apptec.

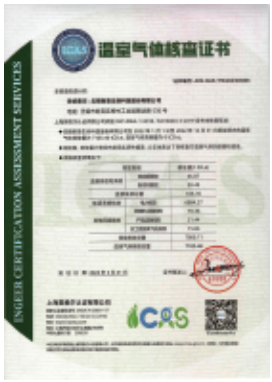
1.4 Regulatory Compliance and Efficiency Advantages

NEST strictly abides by relevant laws and regulations, boasts a stable and professional team for project application, keeps learning regulations and interpreting policies of National Medical Products Administration (NMPA), and maintains close and daily communication with local medical products administrations. Having tracking relevant policies and regulations for a long term and in a professional manner, we have formed an efficient access from application, system assessment to certificate acquisition. Nest has rich experience in Class I medical device filing, Class II medical device registration and Class III medical device product certification.

Nest has also accumulated abundant experience in medical device regulation, certification and registration, especially the successful experience in FDA510K certification and CE MDR certification.

1.5 Green low-carbon recycling economy, sustainable development concepts

In order to fulfill the idea of sustainable development completely, accurately and comprehensively as well as to contribute to the national strategy of emission peak and carbon neutrality, Nest puts energy and resources conservation in the first place, implements all-around resources conservation strategy, continuously reduces energy and resources consumption of unit output and improves efficiency of input-output, advocates a simple, moderate, green and low-carbon lifestyle, promotes advanced low-carbon technologies and shares relevant experience, expedites the green and low-carbon industrial revolution, advances green and low-carbon transformation of enterprise, constructs new industry form of green, low carbon and recycle, and makes contributions to building a community of shared future for mankind. Moreover, Nest takes an active part in forest planting, wet land conservation and other ecological projects to improve the ecological environment, build an image of low-carbon enterprise, enhance the sense of social responsibility of enterprise and realize the long-term sustainable development goal of “Net Zero Emissions” in 2040.



ISO14064-GHG verification

2 Quality Assurance

2.1 Quality Management System

NEST evaluates, controls and manages the quality of its products according to relevant national or international standards. NEST also ensures quality compliance and registration certification to ensure the safety, reliability, and effectiveness of its products, as well as to meet national and international legal requirements. These measures aim to reduce product quality issues and risks and improve production efficiency and management level. If you need to obtain NEST's quality compliance and registration certificates, please refer to the appendix or download them from the official website www.cell-NEST.com.

FDA Registration

Since 2011, NEST has registered and sold its products with the US FDA. Our products comply with relevant US laws, regulations, and technical standards, and possess safety and effectiveness.

YY/T 1768.1-2021; YY/T 1768.2-2021

NEST pen injectors are developed and tested based on the “Needle-based injection systems for medical use - Requirements and test methods” YY/T 1768.1-2021 (ISO 11608-1:2014, NEQ) and YY/T 1768.2-2021 (ISO 11608-2:2012, NEQ) of the People's Republic of China pharmaceutical industry. We strictly adhere to these standards to ensure that our products meet the requirements and demonstrate reliability and effectiveness.

ISO9001、ISO13485

ISO9001 is a certification for quality management systems applicable to organizations of various types and sizes. Its purpose is to help organizations achieve customer satisfaction and continuously improve their business processes. ISO13485 is a certification for medical device quality management systems, applicable to manufacturers, suppliers, and distributors, ensuring that their products comply with relevant regulations and legal requirements for medical devices.

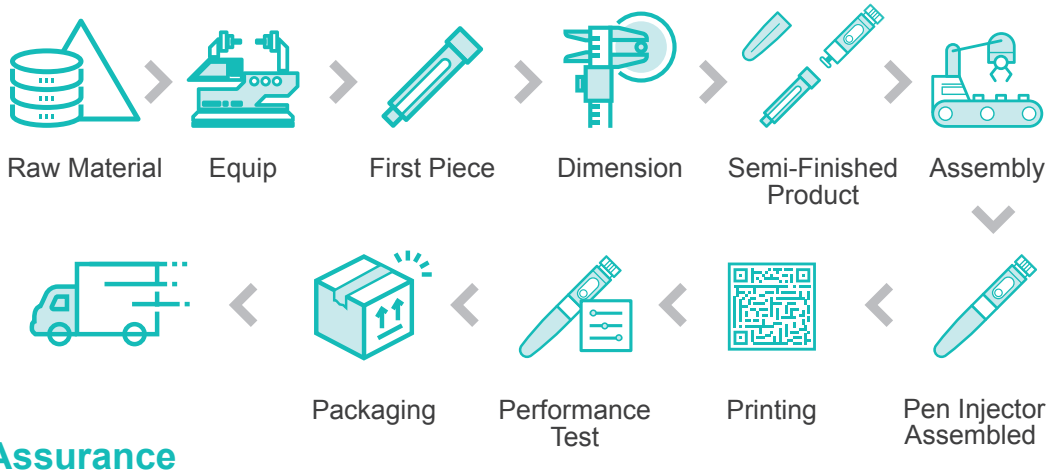
NEST's ISO9001 and ISO13485 certifications are authorized by TÜV Rheinland, an authoritative EU notified body. TÜV Rheinland Group is authorized to conduct assessments for industrial and consumer products to ensure that NEST's products comply with most EU directives and regulations.

Medical Device Manufacturing License

NEST obtained medical device manufacturing license in 2021. We have a wide range of medical products including customizable pen injectors, pen injector assemblies, and disposable nasal spray devices. High-precision pen injectors are difficult medical devices that require high-precision processing equipment and technology and strict quality control. Therefore, obtaining a license to manufacture high-precision pen injectors requires a high level of technical strength and quality assurance. We apply the same technical strength and quality control requirements to our laboratory consumables.

2.2 Process Design Assurance

With the development of the times, people's demands on the quality of drug delivery systems, pharmaceutical packaging and combination products are constantly increasing. NEST's quality management starts at the source. At the mold development and production stages, we use a variety of equipment to ensure the quality of our products, so that "high quality" can be maintained throughout the product and production process. The Quality Assurance Department is involved in all aspects of the production process and works closely with other related departments.



2.3 Quality Center Assurance

As the guardian of quality, the Quality Center comprehensively guarantees the quality of products, which cannot be separated from the close cooperation between the two core areas of Quality Laboratory and Quality Engineering. These two areas of work, like twins, work together to protect the excellent quality of products.

Our quality management team consists of 76 people, including a director, managers, laboratory personnel, quality assurance (QA) personnel, quality control (QC) personnel and quality engineers (QE) and other elites. They not only have profound professional knowledge, but also have been trained in a series of systematic quality tools, such as APQP, FMEA, PPAP, SPC, MSA, 8D, 5W, QC7, etc. Team members are able to skillfully use these tools for continuous improvement and follow the PDCA cycle to ensure the continuous improvement of product quality.

In the quality lab, each working group is responsible for conducting rigorous physical and chemical analyses of raw materials, as well as detailed damage analyses of manufactured components, assembly units or medical products. At the same time, functional tests are carried out on all types of products during the product development phase, and the measuring equipment, measurement records and measurement methods required for this purpose are certified and validated. We develop functional tests not only for individual components, but also for assembly units. For each functional test, we carefully design specific test specifications and set them in accordance with the customer's acceptance criteria. Functionality testing is a key part of product design validation and is performed by a specialized functionality test team. The test results are evaluated and approved by the project quality manager, who is under the supervision of the quality engineering department.

2.4 Validation equipment for production processes

Experience in using Coordinate Measuring Machine System (German ZEISS, CONTURA7/10/6RDS)

In practice, we use Coordinate Measuring Machine System extensively for measuring the dimensions of machining parts of molding tools, fixtures, complex products, and experimental samples. We output and analyze data through computers, which is highly reliable. The Coordinate Measuring Machine adopts high-precision optical positioning technology and advanced data processing technology to ensure the reliability and stability of the measurement data.

Size Scanners (the IM-8030 of Japanese Keyence) for size recognition and modeling

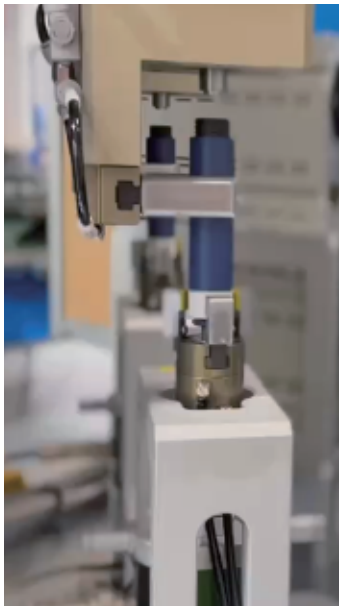
With size scanners, we can measure and analyze material surface dimensions through computer processing alone. We can quickly repeat surface size measurements (such as measuring multiple holes of the same size) by using computer systems.

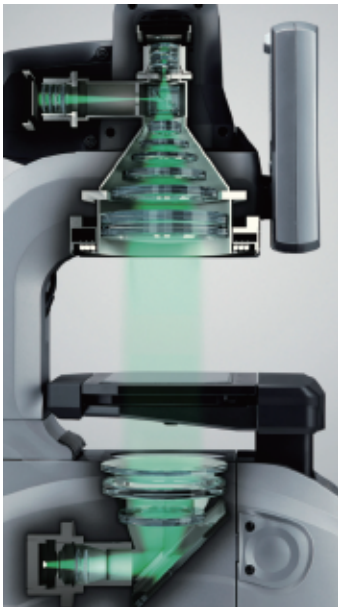
Packaging tear strength tester (YBB-03)

The YBB-03 type pharmaceutical packaging tear strength tester is mainly used for precise measurement of the pressing force and sustained force of pen-type injectors, as well as the tensile strength test, peel test, opening force test, puncture force test of medicinal packaging such as medical rubber stoppers, composite covers, composite films, aluminum foils, PVC rigid sheets, etc. It is also suitable for breaking force test and sliding performance test of prefilled pen injectors and ampoules. This equipment is applicable to research institutions, pharmaceutical companies, inspection and quarantine agencies, etc.

Visual and tactile measurement techniques and industrial computed tomography

A measuring laboratory equipped with modern measuring instruments ensures that precision mold inserts and injection molded parts or assembly units can be measured extremely accurately. The complete part measurement data is recorded in the initial sample test report after the measurement. These include a wide range of multi-sensor CMMs for the measurement of visual and tactile parts, universal measuring microscopes and industrial computed tomography scanners for the non-destructive measurement and testing of individual parts or complete assembly units.





2.5 Raw Material Safety Guarantee

For the certification and validation of pen injectors, we take into account all relevant standards and regulations: GMP Guidelines (GxP), GAMP5 Guidelines, 21 CFR Chapter 820, 21 CFR Chapter 11, as well as the ISO 9001, ISO 13485 standards, the MDD 93/42/EEC regulation, the AMG/MPG/AMWHV regulation.

Incoming control of specific materials, physical and chemical analysis

NEST has implemented strict controls on supplier access and approval of raw materials/packaging materials. We perform detailed material, physical and chemical analyses of plastic pellets and, where necessary, analyze the causes of damaged parts. Our well-equipped laboratory has the capability to perform physico-chemical analysis of viscosity, residual moisture and density. In addition, we are equipped with an infrared spectrometer and thin-section microscope to provide strong technical support for our experiments. Our analytical services are complemented by in-depth expertise in developing and implementing analytical methods that meet the individual needs of our customers.

The company ensures that all raw materials/packaging materials meet product technical requirements through layered control in the following steps:

- Supplier questionnaires
- Supplier on-site audits
- Raw material/packaging material report review
- Raw material/packaging material performance validation
- Raw material/packaging material batch inspection

These measures ensure the stability of the supply chain and the quality of our products. This section will also provide declarations regarding NEST's control over raw materials and packaging materials:

Declaration of Raw Material Compliance: (ROHS, REACH)

The raw material particles used in NEST pen injectors are supplied by manufacturers with relevant reports complying with ROHS and REACH, including but not limited to ABS, PC, PP, etc.

ROHS: NEST strictly complies with the European Union directive "Restriction of Hazardous Substances in Electrical and Electronic Equipment" (2011/65/EU) (ROHS), which aims to control the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers in products.

REACH: NEST strictly complies with the European Union regulation "Registration, Evaluation, Authorization, and Restriction of Chemicals" (2006/1907) (REACH), which controls the substances of very high concern (SVHC) in raw materials.

Laboratory for the analysis of materials dedicated to drug delivery devices and pharmaceutical packaging

2.6 Samples for development, clinical trial studies and stability studies

Validation Program for Pen Injectors and Pen Injector Assemblies

Product Performance Test	Batch Release Test
Injection button trigger force testing	Appearance inspection
Final dose accuracy testing	Cartridge chamber labeling inspection
Free-fall dose accuracy testing	Injection dose labeling inspection
Cool/Standard/Warm ambient environment dose accuracy testing	Injection dose knob stability testing
Dry heat/Frozen atmospheric environment dose accuracy testing	
Vibration test dose accuracy testing	
Cool/Standard/Warm ambient environment injection resistance, leakage check, and needle compatibility testing	
Dry heat/Frozen atmospheric environment injection resistance, leakage check, and needle compatibility testing	
Vibration test injection resistance, leakage check, and needle compatibility testing	
Injection button trigger force testing	
Final dose accuracy testing	
Stability verification testing	
Life cycle testing (Reusable pen injector only)	
Cycled environment testing (Reusable pen injector only)	

The tests are performed in accordance with the national standard YY/T 1768.1-2021 (ISO 11608-1:2014, NEQ) and YY/T 1768.2-2021 (ISO 11608-2:2014, NEQ). For other test reports apart from the ones provided in this chapter, please contact us to obtain them.

2.6.1 Validation program for pen injector assembly

1.Dose accuracy validation test

With reference to the Pharmaceutical Standard of the People's Republic of China "Medical Needle Injection System - Requirements and Test Methods - Part 1: Needle Injection System" (YY/T1768.1-2021), the dosage accuracy test of the disposable injection pen (Model No. NEST-1A) is shown in the following Table 1, and the results of the test meet the requirements of the regulations.

Test item	Test summary	Probability component p	Dose combinations per pen R	Total measurements per V measurement Number of measurements n	Bilateral target K-value	Test basic principle (Refer to YY/T1768.1-2021 standard)
Cool, standard and warm atmospheres	5°C±3°C、23°C ±5°C and 40°C ±2°C, test dose accuracy (DA)	0.975	1	60	2.670	These tests are expected to measure the performance of the pen injector over a range of temperature and humidity variations representative of indoor or outdoor controlled or uncontrolled "in-use" environments. Outdoor conditions include seasonal (winter to summer) variations and indoor conditions include year-round variations in "room temperature".
Free Fall	Test dose accuracy (DA) after a one-meter fall in three directions	0.95	1	21	2.731	The purpose of the free fall test is to verify the performance of the product after landing on impact in the unused condition without the outer packaging (or carrying case). A nominal height of 1m is used (this is the most likely height at which the pen injector will be placed on a table).
Dry Heat/ Freezing	70°C±2°C and - 40°C ±3°C, test dose accuracy (DA)	0.975	1	60	2.670	The test is expected to measure the performance of pen injectors after exposure to extremely hot and cold storage and transportation conditions, as well as extreme behaviors with potential users (e.g., placing a pen injector on the dashboard of a car in hot weather or accidentally storing it in a freezer).
Vibration	Test DA after vibration	0.975	1	20	2.760	The vibration test is expected to simulate ambulatory patient storage, such as when the patient carries the pen injector for use during the day (e.g., on public transportation or while running).
Last dose DA	Test DA for the last dose	0.975	Only the last Unit	60	2.670	The final dose is considered to be as important as any other dose and therefore it is appropriate to meet the same accuracy requirements.

2.Resistance and needle fit and leakage check validation program

With reference to the medical industry standard of the People's Republic of China, "Medical Needle Injection System-Requirements and Test Methods-Part 1: Needle Injection System" (YY/T1768.1-2021), "Medical Needle Injection System-Requirements and Test Methods-Part 2: Needle" (YY/T1768.2-2021), and with regard to the number of samples of the test of injection resistance set internally by the factory, the number of samples for the test of injection resistance and needle adaptability and leakage check of the pen injector is detailed in the following table 1: Injection resistance and needle adaptability and leakage check test. The number of samples for the injection resistance test is set by the factory, and the injection resistance of the pen injector and the needle adaptability and leakage inspection test are shown in Table 1 below:

Dose Accuracy Test item	Test environment	Samples for resistance	Samples for needle fitting	Samples for leakage check
Standard atmosphere	23℃±5℃	10	20	10
Cold atmosphere	5℃±3℃	10	20	10
Warm atmosphere	40℃±2℃	10	20	10
Dry heat	70℃±2℃	10	20	10
Freezing	-40℃±3℃	10	20	10
Vibration	After vibration	10	20	10
Thermal humid	40℃, 93%RH for 96 hours	10	20	10

3.Stability verification

Select 603 pen injectors and place them in an aging chamber (60±2 ℃) for accelerated aging. Leave them in the aging chamber for 28 days (1-year expiration), 85 days (3-year expiration), and 141 days (5-year expiration) respectively. Under each aging condition, take 201 samples, use purified water as the test medium, and perform tests with a BD 31G/5mm needle. The test items include appearance, dosage indication on the cartridge chamber, dosage indication on the injection, stability of the dosage adjustment knob, dosage accuracy in cold/standard/warm atmospheric environments, injection resistance in cold/standard/warm/dry heat/frigid/thermal humid atmospheric environments, free-fall test, dry heat freezing experiment, thermal humid experiment, and leakage test, totaling nine tests. The test results should comply with the standards. (For the complete version of this chapter's test report, please contact us for more information.)

4.Periodic monitoring

According to the standard YY/T 1768.1-2021 (ISO 11608-1:2014, NEQ), periodic monitoring is required every year, excluding stability testing. It involves repeating the verification of product performance for all other test items.

5.Batch release test

Appearance Inspection:According to the performance specifications of the pen injector, under environmental lighting conditions of (215±20) lx and a viewing distance of 40cm to 70cm, a visual inspection is performed on the appearance of the product. The product should be free from defects that affect its appearance, such as burrs, patterns, shrinkage, flow marks, scratches, etc. There should be no cracks on the inside, and the printed markings should be clear. The appearance inspection should comply with the standards.

Cartridge Chamber Dosage Indication Inspection:According to the performance specifications of the pen injector, under environmental lighting conditions of (215±20) lx and a viewing distance of 40cm to 70cm, a visual inspection is conducted on the cartridge chamber. The cartridge chamber should have dosage (IU) indications for the cartridge bottles. The cartridge chamber should be transparent, allowing visual estimation of the volume of medication delivered and the remaining volume of medication. The inspection should comply with the standards.

Injection dose labeling inspection: According to the performance specifications of the pen injector, under environmental lighting conditions of (215±20) lx and a viewing distance of 40cm to 70cm, a visual inspection is performed on the product. The inspection focuses on the injection dosage indication. Through the window, clear observation of the calibration lines corresponding to the set dosage and their corresponding values should be possible. The calibration lines should be evenly distributed, and the numeric values on the injection dosage scale should range from 0 to 60. The inspection should comply with the standards.

Injection Dosage Knob Stability Test:According to the performance specifications of the pen injector, a test is conducted on the stability of the injection dosage knob. Each rotation of one integer scale should produce an audible "click" sound. After setting the injection dosage, it should be allowed to be reset if needed. The test should comply with the standards.

2.6.2 Validation program for pen injector (reusable pen)

1.Dose accuracy validation test

With reference to the Pharmaceutical Standard of the People's Republic of China "Medical Needle Injection System-Requirements and Test Methods-Part 1: Needle Injection System" (YY/T1768.1-2021), the dosage accuracy test of the Reusable Injector Pen Pen is shown in the following Table 1, and the results of the test satisfy the requirements of the regulations.

Test item	Test summary	Probability component p	Dose combinations per pen R	Total measurements per V measurement Number of measurements n	Bilateral target K-value	Test basic principle (Refer to YY/T1768.1-2021 standard)
Cool, standard and warm atmospheres	5°C±3°C、23°C ±5°C and 40°C ±2°C, test dose accuracy (DA)	0.975	1	60	2.670	These tests are expected to measure the performance of the pen injector over a range of temperature and humidity variations representative of indoor or outdoor controlled or uncontrolled "in-use" environments. Outdoor conditions include seasonal (winter to summer) variations and indoor conditions include year-round variations in "room temperature".
Free Fall	Test dose accuracy (DA) after a one-meter fall in three directions	0.95	1	21	2.731	The purpose of the free fall test is to verify the performance of the product after landing on impact in the unused condition without the outer packaging (or carrying case). A nominal height of 1m is used (this is the most likely height at which the pen injector will be placed on a table).
Dry Heat/ Freezing	70°C±2°C and - 40°C ±3°C, test dose accuracy (DA)	0.975	1	60	2.670	The test is expected to measure the performance of pen injectors after exposure to extremely hot and cold storage and transportation conditions, as well as extreme behaviors with potential users (e.g., placing a pen injector on the dashboard of a car in hot weather or accidentally storing it in a freezer).
Vibration	Test DA after vibration	0.975	1	20	2.760	The vibration test is expected to simulate ambulatory patient storage, such as when the patient carries the pen injector for use during the day (e.g., on public transportation or while running).
Last dose DA	Test DA for the last dose	0.975	Only the last Unit	60	2.670	The final dose is considered to be as important as any other dose and therefore it is appropriate to meet the same accuracy requirements.
Thermal humid	Test DA after 40℃, 93%RH for 96 hours	0.95	1	20	2.670	This test is intended to measure the performance of a pen exposed to the same temperature as the dry heat test temperature but at a much higher humidity.

2.2. Resistance, needle fit and leakage check validation program

With reference to the medical industry standard of the People's Republic of China, "Medical Needle Injection System-Requirements and Test Methods-Part 1: Needle Injection System" (YY/T1768.1-2021), "Medical Needle Injection System-Requirements and Test Methods-Part 2: Needle" (YY/T1768.2-2021), and with regard to the number of samples of the test of injection resistance set internally by the factory, the number of samples for the test of injection resistance and needle adaptability and leakage check of the pen injector is detailed in the following table 1: Injection resistance and needle adaptability and leakage check test. The number of samples for the injection resistance test is set by the factory, and the injection resistance of the pen syringe and the needle adaptability and leakage inspection test are shown in Table 1 below:

Dose Accuracy Test item	Test environment	Samples for resistance	Samples for needle fitting	Samples for leakage check
Standard atmosphere	23℃±5℃	10	20	10
Cold atmosphere	5℃±3℃	10	20	10
Warm atmosphere	40℃±2℃	10	20	10
Dry heat	70℃±2℃	10	20	10
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3.Stability verification

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4.Periodic monitoring

According to the standard YY/T 1768.1-2021 (ISO 11608-1:2014, NEQ), periodic monitoring is required every year, excluding stability testing. It involves repeating the verification of product performance for all other test items.

5.Batch release test

Appearance Inspection: According to the performance specifications of the pen injector, under environmental lighting conditions of (215±20) lx and a viewing distance of 40cm to 70cm, a visual inspection is performed on the appearance of the product. The product should be free from defects that affect its appearance, such as burrs, patterns, shrinkage, flow marks, scratches, etc. There should be no cracks on the inside, and the printed markings should be clear. The appearance inspection should comply with the standards.

Cartridge Chamber Dosage Indication Inspection: According to the performance specifications of the pen injector, under environmental lighting conditions of (215±20) lx and a viewing distance of 40cm to 70cm, a visual inspection is conducted on the cartridge chamber. The cartridge chamber should have dosage (IU) indications for the cartridge bottles. The cartridge chamber should be transparent, allowing visual estimation of the volume of medication delivered and the remaining volume of medication. The inspection should comply with the standards.

R&D and Molding Tool Manufacturing

Injection dose labeling inspection: According to the performance specifications of the pen injector, under environmental lighting conditions of (215±20) lx and a viewing distance of 40cm to 70cm, a visual inspection is performed on the product. The inspection focuses on the injection dosage indication. Through the window, clear observation of the calibration lines corresponding to the set dosage and their corresponding values should be possible. The calibration lines should be evenly distributed, and the numeric values on the injection dosage scale should range from 0 to 60. The inspection should comply with the standards.

Injection Dosage Knob Stability Test: According to the performance specifications of the pen injector, a test is conducted on the stability of the injection dosage knob. Each rotation of one integer scale should produce an audible "click" sound. After setting the injection dosage, it should be allowed to be reset if needed. The test should comply with the standards.

Life cycle test: Select a total of 3 products (using new cartridge bottles) that have undergone dosage accuracy and resistance tests in cold, standard, and warm atmospheric environments. Simulate the operation of each structure of the pen injector (excluding the connecting cap, needle, and injection medication). The products are operated 4500 times (1.5 times the expected lifespan). After this operation, perform dosage accuracy and resistance tests again under standard atmospheric environment conditions (23±5 ℃, 50±25 %RH). All products should meet the standard requirements.

Cycled environment test: Select 10 pen injectors fitted with cartridge bottles (without needles) to be pretreated under the following conditions:

a) Alternating 1; [see GB/T2423.4-2008 Fig. 2a]<IEC60068-2-30:2005,Environmental testing-Part 2-30:Tests-Test Db:Damp heat,cyclic(12 h+12 h cycle),IDT

b) (5±3)℃ low temperature (no humidity requirement);

c) (55±2)°C high temperature and (50±25)%RH;

d) After 6 cycling cycles.

According to this operation and then again under the standard atmospheric environment (23 ± 5 ℃, 50 ± 25 % RH), dose accuracy and resistance test, the product are in line with the standard.

As a system supplier, NEST has the ability to design and develop molds independently, and we tailor pen injectors to your specific needs or optimize the layout of injection molded parts. The fact that our design and development experts take the actual manufacturing situation into account during the development phase not only means that development time, costs and project risks can be significantly reduced, but also eliminates the need to optimize polymer processing after product development.

3.1 Experience in developing precision molds

01 Material
Sourcing steel from Sweden, Germany and Japan. Better mold polishing performance and Higher product flatness.

02 Design
Unique cooling and exhaust system

03 Hot Runner
According to the product's thin wall, high permeability, multi-cavity, short cycle time characteristics of the selection of the most suitable product hot runner system

04 Technique
Analyzed with professional analysis software Moldflow

05 Flexibility
Offer customization

4 High-performance automation solutions

For more than 30 years, NEST Mold Design and Manufacturing has been firmly committed to providing external customers with precise and high performance injection mold design and production services. To date, we have produced over 300 molds for a wide range of applications including life science consumables, medical devices, electronic components, and more.

In order to ensure the performance and quality of each set of precision molds, NEST has a professional maintenance team with more than 50 members, most of whom have more than 10 years of rich working experience. Their work ensures that our precision molds have excellent high repeatability, durability and short cycle time.

Especially in the case of high-volume production in the pharmaceutical and healthcare industries, automation that is precisely coordinated with products, projects and processes has a decisive impact on the quality and economic efficiency of production.

Automation is an integral part of our product and process development. Our expertise is embedded in product development as early as the concept and design stage. Automation solutions are not developed for series production, but already in the prototype and pre-production phase, which saves production time. If an external solution has to be introduced for series production, our knowledge and information can also be shared with the manufacturer of the external automation system.

4.1 Pen injector assembly equipment

Reusable pen injector assembly equip

Main Process:

- Feeding with rotor
- Height test
- Press fitting and test
- Gear assembly
- Bracket assembly
- Pen cap assembly
- Goods/defective goods materialization
- In-line press force inspection
- Torque test (Torque value<4N · cm)

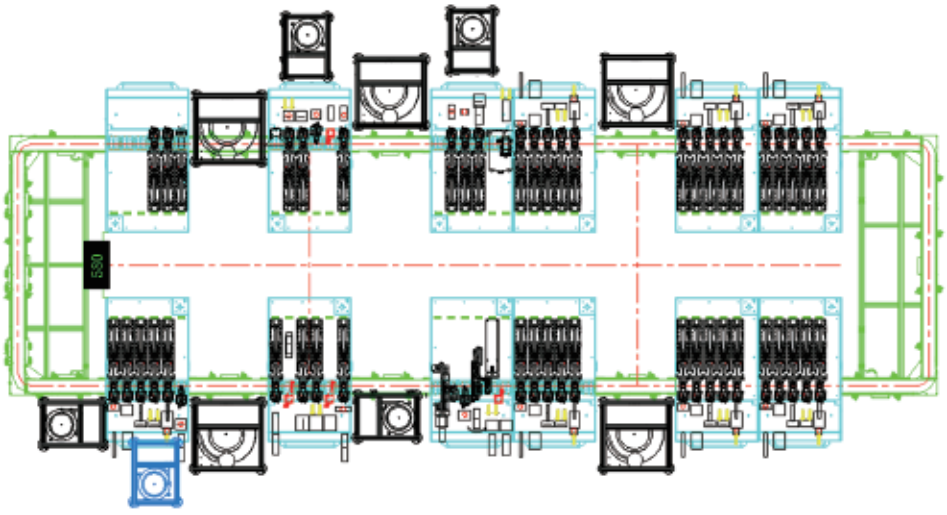
Integration technology and flexible modular, standardized high-speed platforms

Main parameters:

- The equipment is produced with integration technology and flexible modular and stan dardized platform.
- Efficiency: 7 units/minute
- Linear system - smaller footprint
- Progressive investment: Initial investment in a basic machine with a capacity of 7 ppm; next investment in upgrading to FMS 2M or 40 ppm
- Minimalist design, higher machine efficiency
- Dimensions of the machine: 6000mm long, 4500mm wide

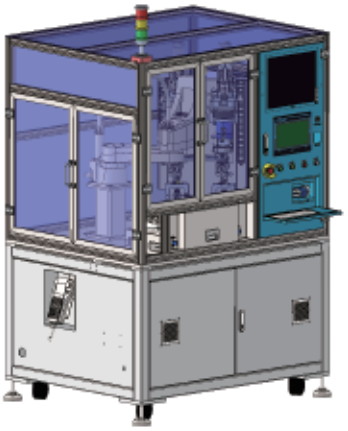
4.2 Assembly equipment for pen injector assemblies

- The device is made of flexible standard modules: 60% are standard platforms and 40% are customized;
- The equipment is fully automatic production method; online torque detection;
- Efficiency is: 100 pcs/min
- Equipment size: length 8000mm, width 5500mm;
- Linear system: smaller footprint, higher flexibility;
- Carrier: modular, can be changed at any time according to different products, easy to operate;
- Progressive investment: the current efficiency is 100ppm for the initial investment. Future equipment can be upgraded to 160ppm;
- Automatic feeding: round pieces are fed by low-noise, non-abrasive step feeding; some vibrating plate applications can also realize automatic clearing function; the equipment effectively ensures that all pushers are at a uniform position height.



Torque, press force and dose accuracy testing equipment

- Torque, press force and accuracy testing equipment;
- Testing efficiency is: 8pcs/min;
- Torque testing accuracy: 0.1% F.S (approximately equal to 0.2N.CM);
- Press force testing accuracy: 0.25% F.S (approximately equal to 1.25N), to ensure that the injection force of each pen is less than 10N;
- Injection accuracy testing: 0.001mm;
- All testing data are displayed in curves (data storage is traceable).

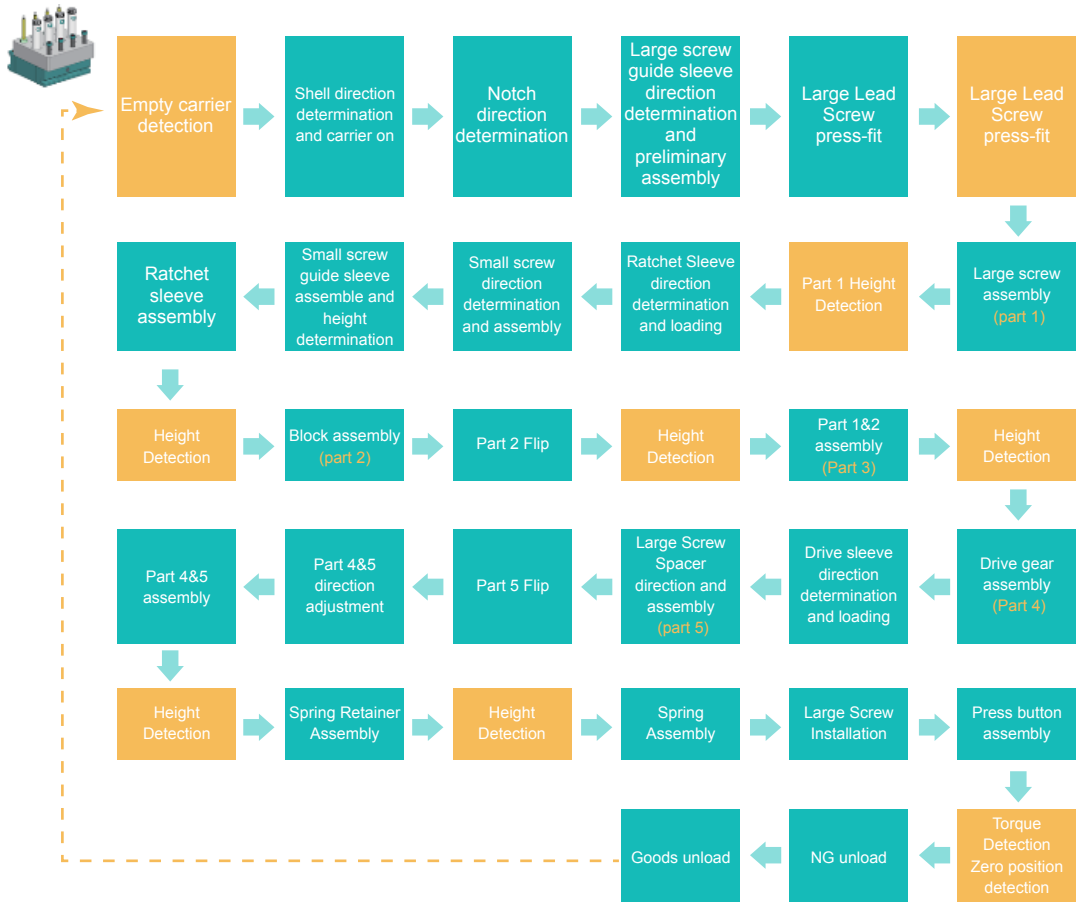


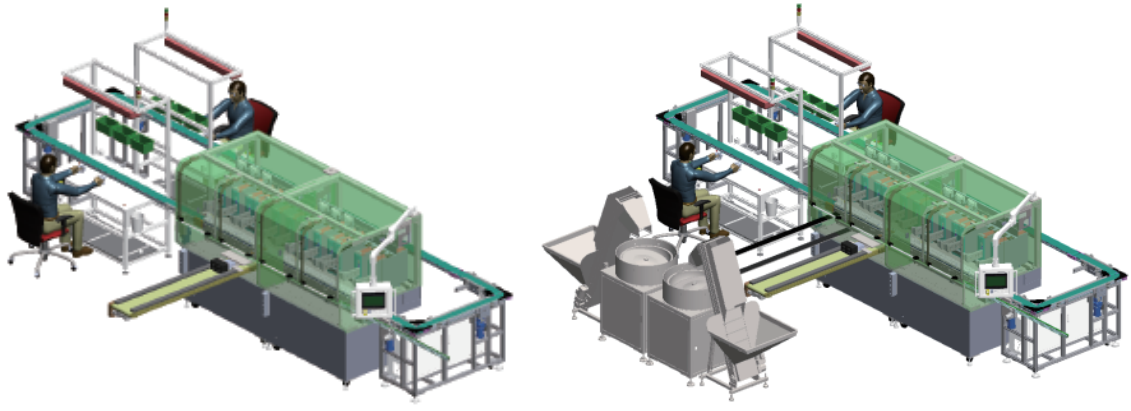
4.3 Total Solution for Pen Injector Assembly Line

——Modern means of production for the pharmaceutical and healthcare industries

Automated test systems linked to automated assembly systems

We plan, procure or develop component-specific automated assembly systems, automated test systems, rotary table systems, vision systems, linear systems, robots for inserting and removing components, packaging systems, pre-production equipment and pharmaceutical assembly systems that are tailored to the individual requirements of our customers.



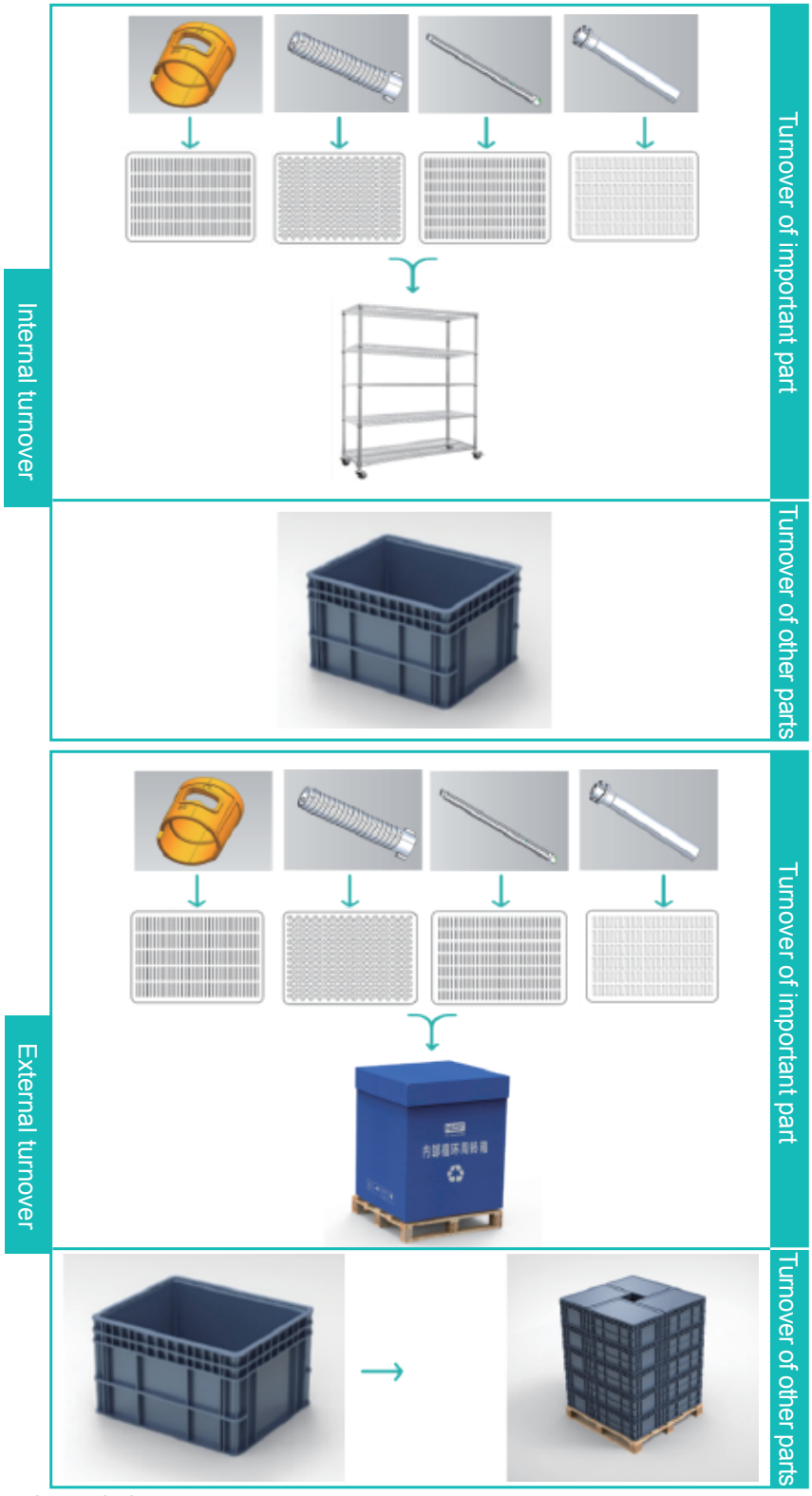


Incremental investment, bottom to top production → reserved for upgrading workstations

Automation solutions with quality levels that meet globally harmonized standards

Disassembly and handling of injection molds with pallet loaders (palletizers)

All the automation solutions we develop and use are of a high level of quality in accordance with worldwide uniform standards.



5 Production Environment Control

Qualification of 100,000 class and 10,000 class Level Clean-Rooms

NEST has multiple clean-rooms that meet ISO14644 Class 7/8 standards. They undergo periodic monitoring by third parties to ensure compliance with product manufacturing and packaging requirements. Please contact us through our official website or email to obtain the clean-room qualification testing report.

Methods for Clean-Room Environmental Control

NEST conducts periodic monitoring of dust particles, airborne bacteria, settle plate counts, air exchange rates, temperature, humidity, pressure differentials, and compressed air in clean-rooms, in accordance with ISO14644 requirements and company procedures, to ensure compliance with regulatory requirements for clean-room environments.

Qualification of Sterility Testing Laboratory

NEST has a Biosafety Level 2 (BSL-2) sterility testing laboratory. It conducts testing of the production environment according to clean-room environmental testing procedures to ensure the safety and reliability of the production environment, and that the final products meet customer requirements.

Purified Water System Validation

NEST has multiple purified water systems used for cleaning clean-rooms, clean-room garments, and tools, ensuring the quality of water used in clean-rooms. The company conducts periodic water point testing to test the properties, acidity/alkalinity, ammonia, conductivity, nitrates, nitrites, oxidizable substances, non-volatile matter, heavy metals, and microbiological limits of purified water, to ensure compliance with the requirements of the Chinese Pharmacopoeia (2020 edition) and European Pharmacopoeia(2020) <Purified Water> section.

6 Project Management

6.1 Product Process Control

During the product validation process, NEST will test all performance items of the product according to internal product technical requirements to ensure that the product meets the design requirements. NEST products go through product design validation, process window validation, performance validation, small-batch trial production, and three-batch production tracking during the development stage to ensure that the products are produced stably and reliably, meeting the product design requirements.

After the product validation is completed and mass production is achieved, some of the early-stage validated product performance test items will be transformed into periodic monitoring and batch testing items to control the consistency of product quality. Periodic monitoring is conducted regularly based on different products and test items, while batch testing is conducted before each batch of product processing and release to ensure that any product quality issues are promptly identified, intercepted, and corrected during the production process.

6.2 Product Performance Validation

Product performance validation refers to a series of tests and validations to check whether the product meets the predetermined performance parameter requirements and user usage needs. The results of the validation can be used to determine whether the product can enter the next stage of development or production. These validations include, but are not limited to:

- Application performance validation of finished products
- Shelf life validation of finished products
- Transportation validation of finished products

6.3 Periodic Monitoring

Periodic monitoring of products refers to regular testing and evaluation of finished products to ensure that they continue to meet quality and performance requirements during use. This type of monitoring helps identify problems with the production process or quality testing process that have a moderate level of risk and take necessary measures for repair or replacement in a timely manner. Periodic monitoring varies depending on the product type and purpose, including, but not limited to:

- Dose Accuracy Testing
- Resistance Testing
- Vibration Resistance Testing
- Stability Testing

6.4 Batch Release Test

Process inspection and batch release test are important methods for product quality management, which can control the quality of semi-finished products and pre-released finished products, ensuring stability and consistency of product quality. The advantage of batch release test is the ability to detect problems as soon as possible throughout the entire process, thereby reducing production costs and improving product quality. These testing items include, but are not limited to, the following for semi-finished and finished products:

- Free fall test
- Trigger force test
- Stability test of injection dose knob
- Appearance and packaging inspection

7 Global Warehousing and Logistics Capabilities

7.1 Supply Chain Stability and Lead Time

To ensure the stability of the supply and timely delivery, NEST employs the following measures to manage the supply chain and lead time:

- Long-term supply contracts: NEST signs long-term supply contracts with customers to ensure stable supply over a certain period of time.
- Safety stock: To address unforeseen circumstances during production, the company maintains a certain quantity of safety stock.
- Timely scheduling: Based on customer orders and inventory status, NEST adjusts production plans promptly to ensure timely delivery.

7.2 Traceability

NEST maintains the following methods to trace the production and transportation processes of its products:

- Batch information: Information about each product batch is recorded through batch coding, which enables traceability of key process inspection data and test results. Customers can use this information to trace the production of the product.
- Production records: In NEST's production process, process inspection data is retained at each process step, including raw materials, injection molding, and other product processing techniques. This data can be used to trace the production of the product.
- Sample retention: Samples are retained for each batch of products, allowing customers to trace the production of the product.
- Transportation process inspection: In addition to the production process, NEST also conducts inspections of the transportation process to ensure that the products are not damaged or compromised in quality during transportation.

7.3 Shelf Life

NEST determines the shelf life of products by conducting accelerated aging tests in accordance with YY/T 0681.1-2018 or ASTM F1980. The start time for calculating the shelf life is the production period of the product, as indicated by the batch-numbered accompanying COA/COC of NEST products. The duration of the shelf life for general products can be found in the COA/COC and the official product technical documents on the website.

Unless otherwise specified, the general storage conditions for NEST medical devices and pharmaceutical packaging materials are a relative humidity not exceeding 80%, in a room temperature (10-30℃), and in a light-protected environment. During transportation, precautions should be taken to prevent mechanical collisions or contact with sharp objects, avoid exposure to sunlight and rain, and ensure that the packaging is intact and the products are not contaminated.

Reusable Pen Injector Customization Solution

Product	Reusable Pen Injector 	
Client		
Intended Application		
Appearance	Body Color	☐Regular：Blue ● ☐Other：
	Dosage Adjustment Knob Color	☐Regular：White ◯ ☐Other：
	Window	☐Small Dosage Display Window ☐Large Dosage Display Window
	LOGO	☐Without LOGO ☐Customizable Pattern
Dose & Graduation	Min. Single Dose	☐0.01mL ☐0.0075mL ☐Other：
	Max. Single Dose	☐60 U ☐75 U ☐80 U ☐Other：
	Graduation	☐mg ☐mL
		Pharmaceutical warehouse printing requirements：
Packaging	☐Deluxe：☐Plus (4 Needles+ 1 Cartridge) ☐Regular(3 Needles+ 1 Cartridge)	
	Other：	
User Manual	☐Customizable	
Others		

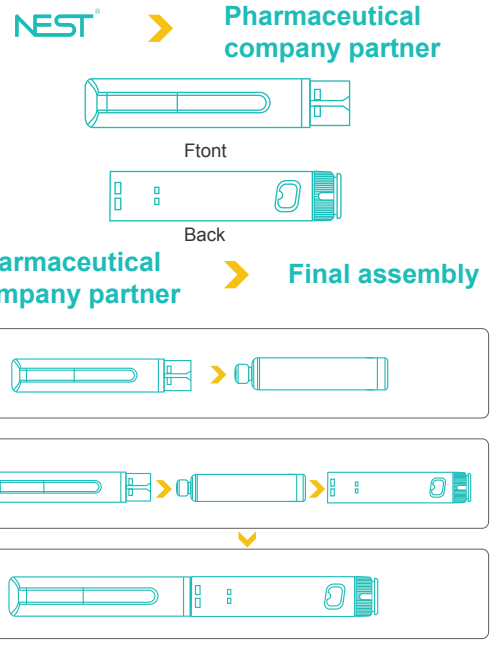
Small Window

Large Window

Picture for demonstration only; the set doesn't include needles and cartridge.

Disposable Pen Injector Customization Solution

Product	Pen Injector Assembly	
Client		
Intended Application		
Appearance	Color	☐Regular：☐Pink (36U) ☐Purple (37U) ☐Yellow (50U)
		☐NEST Green (60U) ☐Orange (74U) ☐Green (75U)
		☐Blue (80U)
		☐Other: Pantone Color Code
	LOGO	☐Without LOGO ☐Customizable Pattern
	Cap	☐Long ☐Short
Dose	☐Regular：☐36 U ☐37 U ☐50 U ☐60 U ☐74 U ☐75 U ☐80 U ☐Customizable：Min： Max：	
Graduation	☐Unit：☐mg ☐iu ☐mL ☐Customizable：	
	Pharmaceutical warehouse printing requirements：	
For Rubber Stopper	☐Long ☐Short	
For Cartridge	☐3.0 mL ☐1.5 mL	
Packaging	☐Trayed：Body 50 pcs/tray, Cap 50 pcs/tray, 200 sets/case ☐Automatic Transfer Case ☐Other：	
User Manual	☐Customizable	
Others		



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