Pinjection
Medical Device Technologies

Injection Pen

DESIGNED FOR EASE OF USE

- Over 20 design specifications to improve patient usability and satisfaction,
- Features to improve usability by mildly-impaired patients.

OPTIMIZED FOR RELIABILITY

- Improved Dosing Accuracy well within ISO standards,
- Several design improvements to enhance mechanism,
- Careful design and manufacturing processes,
- Rigorous testing.

Versatile *self-injection* drug delivery device

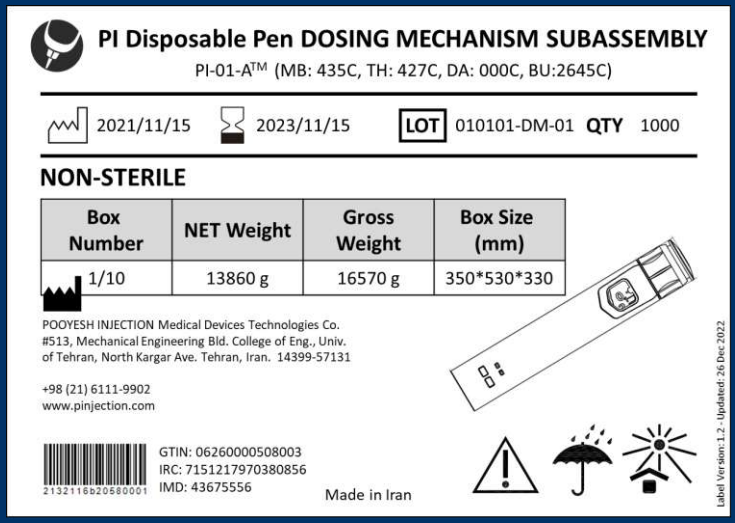
Compliant with:
- ISO 11608,
- ISO 13485, and
- ISO 14971,

to verify that the product and the process meet regulatory agency expectations.

www.pinjection.com

Key Parameters

Parameter	Remarks	Standard
classification	class C needle-based injection system	ISO 11608-1 revision 2022
	Class IIb	rule 6, ANNEX IX, MDD
cartridge size	3 mL cartridge of 100 units/mL (U-100)	ISO 11608-2
needle type	single-use detachable and disposable pen needle	ISO 11608-3
dosing accuracy	$bias + 3 \times variance \leq 5\%$	ISO 11608-1
dosing Increments	$10\ \mu l$	
dosing range	$10 - 600\ \mu l$	
injection force	$\leq 20N$	
material, color, print	customizable	



Packaging Specifications

- Pen parts are delivered in three separate boxes:
  - Dosing Mechanism,
  - Cartridge Holder,
  - Pen Cap.
- Each box contains 20 thermoform trays each holding 50 parts. (a total of 1000)
- Parts are packaged in a rugged three-layer cardboard.
- One batch can contain 10,000 to 100,000 pens.
- One shipping container can hold 500,000 pens.
- Can be shipped by land/air/sea.
- We accept orders to assemble drug cartridges into pens.

Everything revolves around patient safety and satisfaction.

Design specifications

Dosing Mechanism

- Multiple injections per pen (a total injection of 3.00 mL)
- Variable dosing between 0.01 to 0.60 mL per injection
- Precise dosing accuracy compliant with ISO 11608-1
- High-contrast and Large dose markings for improved visibility
- Clear audible and tactile clicks when changing the dose
- Reduced injection force (< 20 N)
- Soft and easy two-way mechanism for dose selection (low-torque)
- Safety locking mechanism after the drug is fully injected

Cartridge holder

- Compatible with standard pen needles compliant with 11608-2
- Compatible with standard 3ML cartridges compliant with 11608-3
- Easy needle attachment and removal
- Strong needle grip for increased reliability
- Transparent Polypropylene for hygiene and visibility
- Post-injection remaining dose indicator
- Geometrical features for fast and reliable cartridge assembly

Pen Cap

- Clicking sound when attached
- Clip for easy hold onto pocket and protection against rolling off surfaces
- Extra room for an attached needle
- Strong grip onto the pen

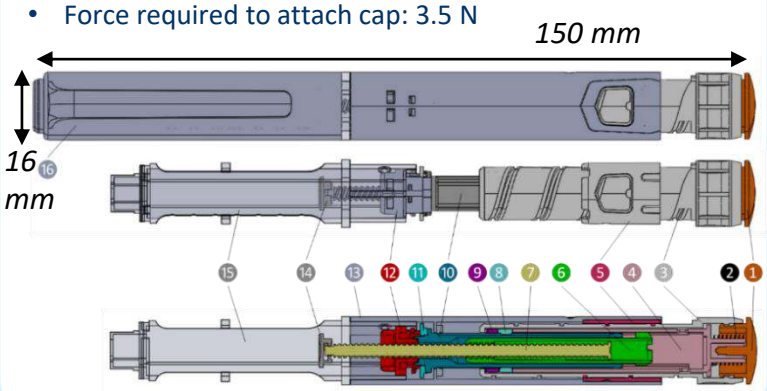
Dosing Tests

Our pen passes rigorous dosing accuracy tests. According to certified results, our dosing accuracy falls well within the ISO-11608 standard range. Moreover, our pens pass dosing accuracy tests after exposure to stress tests:

- Storage at -20°C or 70°C,
- Within an environment of 0°C or 40°C,
- After mechanical vibration from 3Hz to 300Hz,
- After 1m free fall on a hard surface.

Functional Tests

- Torque required for dose selection: <0.01 Nm
- Force required for injection: <20 N
- Force required to attach holder to dosing: <80 N
- Force required to remove holder from dosing: >150 N
- Torque required to attach needle: < 0.01 Nm
- Torque required to strip needle screw: > 0.5 Nm
- Torque required to break pen after end of use: >2.5 Nm
- Force required to remove injection button: >100 N
- Force required to remove cap: 3.5 N
- Force required to attach cap: 3.5 N



Market History

- Used in marketed drug combination products in the middle east.
- Post Market Clinical Follow-up (PMCF) completed and documented.
- IFDA approved since May 2022.
- Implemented and maintained quality management system for disposable injection pens, certified by CISQ/IMQ.

We can customize

1- Colors, 2- Prints, 3- Dosing units, 4- Cartridge size.

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Company Profile

Pinjection is a Private Joint Stock company that specializes in:

- Research and development of high-precision plastic-based injection devices,
- Mass production of high-precision injection pens including:
  - Production of medical-grade plastic-based components,
  - Assembly of components into final products, and
  - Quality control of medical devices.
- Design and development of process machinery for production line including:
  - High-precision plastic injection molds, and
  - assembly line for production.

Pinjection has a strong human capital in high-precision manufacturing, automation and robotics. Pooyesh injection employs high standards to maximize safety and user satisfaction.

Key benefits

- Designed for a wide range of injectable pharmaceuticals that require variable dosing, including: Insulin analogs, hormones, monoclonal antibodies, and biopharmaceuticals,
- Adjustable colors, prints and physical features to support self-injection,
- Optimized for ease-of-use and reliability,
- Comes with regulatory and technical documentation including but not limited to:
  - Technical File
  - Instructions for Use (IFU)
  - ISO 11608 lab test reports
  - R&D documentation

Availability

- Samples readily available
- Available in a range of color and print combinations

CSQ ISO 13485

Medical Devices Quality Management Systems

CERTIFIED IQNet MANAGEMENT SYSTEM

Certified Management System

دانش بنیان

مرکز شرکت های دانش بنیان

Registered Knowledge Based Company

Certificate IMED

IMED National Medical Device Directorate IR.IRAN

Certified by Iran Medical Devices Directorate

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