



SPECIFICATION

PEN INJECTOR

Applicable to:

QCD, QAD, Production Department

Instead of: СП-0.2058.05-2-135, ред. 02

Valid until:

21.04.25

Copy №:

Attachmants:

Position	Date	Signature	Full Name
Prepared by:			
Quality engineer	07.04.25		Т.А. Лукьянчик
Agreed by:			
Deputy Head of QCD	08.04.25		О.В. Ничипорова
Head of QC Department	08.04.25		Е.А. Галейша
Deputy Chief Technologist	08.04.25		Л.В. Дьячкова
Approved by:			
Deputy General Director of Quality Control Department	12.04.25		В.Н. Стежка



PEN INJECTOR

Supplier: *according to the approved "List of Suppliers / Manufacturers of initial and Packaging Materials"*

Sampling is carried out according to: SOP-0.2200.00.00-2-001

Sample quantity (mass, volume) for testing: according to the approved "Sampling Plan"

Internal code:

27115 – Pen Injector

Beijing Gangan Technology Co., Ltd., China

Gangan Medical Technology Jiangsu Co., China

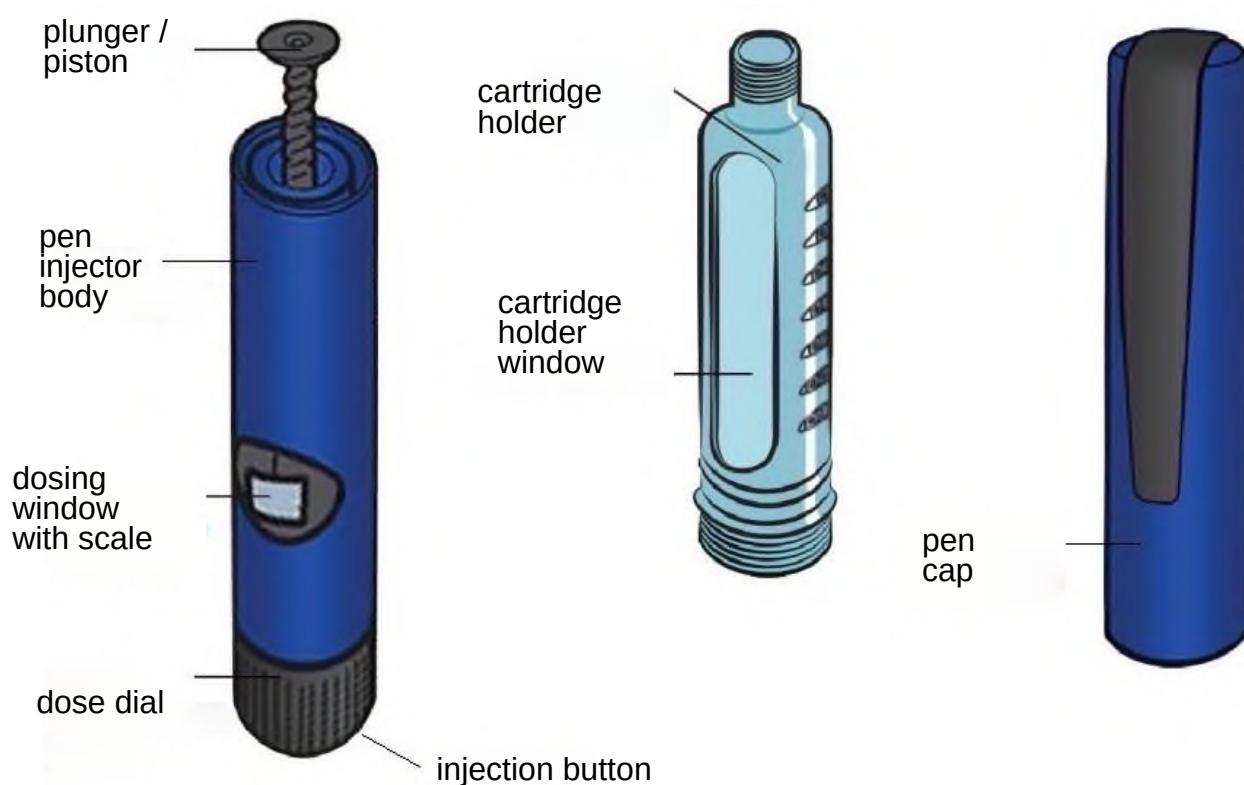


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№	Parameter Name	Acceptable Limits	Control Methods / Testing Procedures
1.	Appearance. Main function control	Test samples must comply with the requirements of: СИИК-0.2058.05-2-032, СИ УМ-0.2058.05-2-135 (Figure 1, Table 1, Table 2)	Visual СИИК-0.2058.05-2-032 СИ УМ-0.2058.05-2-135
2.	Storage	Protect from impacts. Packaged products shall be stored in well-ventilated enclosed premises at temperatures from -40 °C to +70 °C and relative humidity not exceeding 70%.	
3.	Shelf life	In accordance with the manufacturer's certificate.	

Note: All regulatory documents referenced in this specification shall be used with amendments актуальными as of the testing date.

Figure 1. Pen injector (appearance)





PEN INJECTOR

Table 1. Classification of Defects

Defects	Defect description
Critical	- color non-uniformity - very heavy contamination (dust, grease, oil residues) - stains or foreign inclusions with diameter greater than 1 mm - inability to connect pen injector elements - missing parts of the pen injector - tears, chips, broken parts of the pen injector
Major	- incorrect or incomplete assembly of the pen injector hindering its use
Minor	- folds, scratches, rough surface - slightly dusty or contaminated products - stains or foreign inclusions with diameter less than 1 mm

Table 2. Acceptance Numbers

Defects					
Critical		Major		Minor	
Acceptance number	Rejection number	Acceptance number	Rejection number	Acceptance number	Rejection number
0	1	1	2	5	6



QCD

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INSPECTION AND REVISION RECORD

Revision	Effective from	Reason for revision	Checked without changes	
			Date	Signature
01	23.06.20	NEW		
02	25.09.24	Document update. Addition of alternative manufacturer Gangan Medical Technology Jiangsu Co., Китай.		
03		Document update. Addition of reference to СПИК-0.2058.05-2-032. Change of document title and coding.		

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DOCUMENT FAMILIARIZATION SHEET

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Revision: 03

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