

天津市麦迪克医用器材有限公司

TIANJIN MEDIC MEDICAL EQUIPMENT CO., LTD.

CERTIFICATE OF ANALYSIS

Product name:		DISPOSABLE SYRINGES		LOT:		20250215				
Quantity:		639800PCS		Specification :		5mL 22GX1 1/2				
Inspection Date:		2025.2.18-2025.2.25		Date of report:		2025.2.25				
Basis of inspection:		FQC-ZSQ "Infusion Set Finished Product Inspection Procedures"								
Inspection Items		Project description		IL	AQL	Sam ple	Acc./ Rej.	Def ect	Result	
									Qu alified √	Un qua lified×
1. App eara nce	1.1	Under the illumination of 300lx ~ 700lx, observe with the naked eye with normal vision or corrected to normal vision. The surface of the syringe in contact with the injection in normal use should be clean, free of particles and foreign bodies.		S-3	0.65	80	[1,2]	0	√	
	1.2	The syringe should have no raw edges, burrs, plastic flow, defects.		S-3	0.65	80	[1,2]	0	√	
	1.3	The jacket of the syringe should be transparent enough to clearly see the reference line		S-3	0.65	80	[1,2]	0	√	
	1.4	When the piston is fully pushed to the bottom of the jacket, the lubricant should not enter the cone head cavity		S-3	0.65	80	[1,2]	0	√	
	1.5	The surface of the syringe core rod should be free of burrs and sharp edges, and the pressing hand should have sufficient size and shape strength to hold the syringe firmly when it is used		S-3	0.65	80	[1,2]	0	√	
	1.6	The syringe core rod should be consistent with the customer's confirmation sample or Pantone color card number		S-3	0.65	80	[1,2]	0	√	
	1.7	The layout and color of the scale line should be consistent with the customer confirmation sample or Pantone color card number		S-3	0.65	80	[1,2]	0	√	
	1.8	Needle holder and sheath should be free from burrs, burrs, plastic flow, defects and other defects		S-3	0.65	80	[1,2]	0	√	
	1.9	The tip of the needle examined with a 2.5x magnifying glass should be sharp and free of burrs, burrs, bent hooks, flat heads, and/or other defects		S-3	0.65	80	[1,2]	0	√	

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	1.10	Observe with normal or corrected vision that there is no visible accumulation of silicone oil on the outer surface of the needle	S-3	0.65	80	[1,2]	0	√	
	1.11	The inside of the needle should be cleaned by mixing the glycerin and alcohol 1:1 evenly, then injecting 5mL of the mixture through the syringe with a clean syringe. Observed with normal or corrected to normal vision, the mixture flowing through the inner wall of the syringe should be free of foreign bodies and dirt	S-3	0.65	80	[1,2]	0	√	
	1.12	Needle seat color: <u>black</u>	S-3	0.65	80	[1,2]	0	√	
2. Size	2.1	Measuring dew needle length: Standard length <u>38</u> (+1.5,-2.5) mm	S-2	2.5	20	[1,2]	0	√	
	2.2	Outer diameter of needle tube: <u>0.698~0.730</u> mm	S-2	2.5	20	[1,2]	0	√	
	2.3	The hole diameter of the cone head should not be less than 1.2mm	S-2	2.5	20	[1,2]	0	√	
	2.4	The outer cone joint of the cone head of the syringe and the inner cone joint of the needle holder shall comply with the regulations of ISO594-1 or ISO594-2	S-2	2.5	20	[1,2]	0	√	
	2.5	The length of the syringe should be such that the maximum available capacity of the syringe is at least 10% greater than the nominal capacity length	S-2	2.5	20	[1,2]	0	√	
	2.6	The hand press spacing should be greater than <u>8</u> mm	S-2	2.5	20	[1,2]	0	√	
	2.7	Ruler length: <u>41.40</u> mm	S-2	2.5	20	[1,2]	0	√	
3. Phys ics Perf orma nce	3.1	The rigidity of the needle tube	—	—	—	[0,1]	0	√	
	3.2	The toughness of the needle tube	—	—	—	[0,1]	0	√	
	3.3	Corrosion resistance of the needle	—	—	—	[0,1]	0	√	
	3.4	The connection firmness meets the standard	S-2	2.5	20	[1,2]	0	√	
	3.5	The piercing force meets the standard requirements	S-2	2.5	20	[1,2]	0	√	
	3.6	The patency of needle tube meets the requirements	S-2	2.5	20	[1,2]	0	√	
	3.7	The injection needle is well matched with the syringe, shall not fall off, and does not leak	S-2	2.5	20	[1,2]	0	√	
	3.8	The needle base should be well matched with the sheath, the sheath should not fall off naturally, and the separation force of the two should not be greater than 15N	S-2	2.5	20	[1,2]	0	√	
	3.9	The tightness of the body meets the requirements	S-2	2.5	20	[1,2]	0	√	
	3.10	The sliding performance value meets the requirements	S-2	2.5	20	[1,2]	0	√	
	3.11	Capacity tolerance (volume less than half of nominal capacity) $V_0-V_i: V_0*1.5\%+V_i*1\%$, where $V_0: 2\text{ml}$	S-2	2.5	20	[1,2]	0	√	
	3.12	Capacity tolerance (volume greater than or equal to half the nominal capacity) $V_0-V_i/V_i: \pm 4\%$, 其中 $V_0: 5$	S-2	2.5	20	[1,2]	0	√	

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		ml							
	3.13	Maximum residue: <u>0.075</u> ml	S-2	2.5	20	[1,2]	0	√	
	3.14	After the fit of the jacket and the piston assembly, the piston assembly should not move due to its own and the quality of the water	S-2	2.5	20	[1,2]	0	√	
	3.15	Packing seal tightness	S-2	2.5	20	[1,2]	0	√	
	3.16	Packaging seal dyeing penetration test	S-2	2.5	20	[1,2]	0	√	
4. Chemistry Performance	4.1	The pH meets the requirements: the difference between the test solution and the same batch of control solution shall not be greater than 1.0	—	—	25	[0,1]	0	√	
	4.2	Extractable metal content: The total extractable metal content in the test liquid shall not exceed 5μg/mL	—	—	25	[0,1]	0	√	
	4.3	Easy oxide: test liquid and the same batch of control liquid, 0.002mol/L of potassium permanganate solution consumption difference should not exceed 0.5mL.	—	—	25	[0,1]	0	√	
	4.4	Ethylene oxide residue standard (< 10μg/g)	—	—	25	[0,1]	0	√	
5. Biological Performance	5.1	Product sterility (BI culture release)	—	—	—	All qualified	0	√	
	5.2	Product endotoxin less than 0.5EU/mL.	—	—	—	All qualified	0	√	
6. Packaging	6.1	The printing content of the outer box is clear and error-free	S-2	2.5	5	[0,1]	0	√	
	6.2	Small box printing content is clear and error-free	S-2	2.5	5	[0,1]	0	√	
	6.3	Small boxes print clearly and error-free content	S-2	2.5	20	[1,2]	0	√	
	6.4	The outer case is intact and securely packed	S-2	2.5	5	[0,1]	0	√	
Conclusion		<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified							
Remarks									

Inspection:

Approved:

