

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:		20250220				
Quantity:		190800PCS		Specification :		2mL 23GX1 1/4				
Inspection Date:		2025.2.17-2025.2.24		Date of report:		2025.2.24				
Basis of inspection:		FQC-ZSQ "Inspection Procedures for Finished Syringe "								
Inspection Items		Project description		IL	AQL	Sam ple	Acc./ Rej.	Def ect	Result	
									Qu alif ied √	Un qua lifi ed×
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	20	[0,1]	0	√	
	1.2	The syringe should have no raw edges, burrs, plastic flow, defects.		S-3	0.65	20	[0,1]	0	√	
	1.3	The barrel of the syringe should be transparent enough to clearly see the graduation line		S-3	0.65	20	[0,1]	0	√	
	1.4	When the rubber gasket is fully pushed to the head of the barrel, the lubricant should not enter the cone head cavity		S-3	0.65	20	[0,1]	0	√	
	1.5	The surface of the syringe plunger should be free of burrs and sharp edges, and the handle should have sufficient size and shape strength to hold the syringe firmly when it is used		S-3	0.65	20	[0,1]	0	√	
	1.6	The syringe plunger should be consistent with the customer's confirmed sample or Pantone color card number		S-3	0.65	20	[0,1]	0	√	
	1.7	The layout and color of the scale line should be consistent with the customer’s confirmed sample or Pantone color card number		S-3	0.65	20	[0,1]	0	√	
	1.8	Needle seat and cover should be free from burrs, plastic flow and other defects		S-3	0.65	20	[0,1]	0	√	
	1.9	The tip of the needle examined with a 2.5x magnifying glass should be sharp and free of burrs, bent hooks, flat heads, and/or other defects.		S-3	0.65	20	[0,1]	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	20	[0,1]	0	√	
	1.11	The inside of the syringe should be clean. Mixing glycerol and alcohol 1:1 evenly, and then use a clean syringe to inject 5mL of the mixed solution through the injection needle. Observing with normal or corrected to normal vision, the mixture flowing through the inner wall of the needle should be free of foreign objects and dirt.	S-3	0.65	20	[0,1]	0	√	
	1.12	Needle seat color: <u>blue</u>	S-3	0.65	20	[0,1]	0	√	
2. Size	2.1	Exposed needle length: Standard length <u>32</u> (+1.5,-2.5) mm	S-2	2.5	20	[1,2]	0	√	
	2.2	Outer diameter of needle tube: <u>0.600~0.673</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 conical joint of the syringe and the inner conical joint of the needle holder should comply with the provisions of GB/T1962.1 or GB/T1962.2.	S-2	2.5	20	[1,2]	0	√	
	2.5	The maximum usable capacity of the syringe barrel is at least 10% longer than the nominal capacity length.	S-2	2.5	20	[1,2]	0	√	
	2.6	The handle width should be larger than <u>8</u> mm	S-2	2.5	20	[1,2]	0	√	
	2.7	Ruler length: <u>31.47</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 seat should be well matched with the cover, the cover should not fall off naturally, and the separation force of the two should not be larger than 15N.	S-2	2.5	20	[1,2]	0	√	
	3.9	The tightness of the product 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) $V_0-V_i: V_0*1.5\%+V_i*2\%$, where $V_0: 0.5$ ml	S-2	2.5	20	[1,2]	0	√	
	3.12	Capacity tolerance (volume greater than or equal to half the nominal capacity) $V_0-V_i/V_i: \pm 5\%$, where $V_0: 2$ ml	S-2	2.5	20	[1,2]	0	√	

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	3.13	Maximum residue: <u>0.07</u> ml	S-2	2.5	20	[1,2]	0	√	
	3.14	After the fit of the barrel and the assembled piston and plunger, the piston and plunger should not move due to its own and 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 carton is clear and error-free	S-2	2.5	5	[0,1]	0	√	
	6.2	The printing content of the small box is clear and error-free	S-2	2.5	5	[0,1]	0	√	
	6.3	The printing content of the inner packaging is clear and error-free	S-2	2.5	20	[1,2]	0	√	
	6.4	The outer carton is undamaged and securely packed.	S-2	2.5	5	[0,1]	0	√	
Conclusion	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified								
Remarks									

Inspection:

Approved:

