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Certificate of Analysis for Hemodialysis Blood Tubing Sets

OCI/TXGL-J 001-R03_A01

Product Name	Hemodialysis Blood Tubing Sets			Report No.	CA25112002
Model	OCI-BD-D-A	LOT NO	251011	Representative Sample No.	18
Production Date	2025.10.26	Expiry Date	2028.10.25	Total Quantity	6000
Sterilization LOT NO	2510029/2510030	Sampling Date	2025.11.20	Report Date	2025.12.25

Testing Basis			SOP for Hemodialysis Blood Tubing Sets	
S/N	**Test item**	**Standard clause**	**Standard requirement**	**Testing result**
1	Appearance	3.1	The tube wall shall be soft and smooth, free of bubble, obvious mechanical impurity, foreign matter, twisting or bending. The thickness of the pipe wall shall be uniform by visual inspection, and its transparency shall ensure that bubbles can be found.	Meet the requirements
		3.1.1	The tube shall be transparent, the inner and outer surfaces of the tube shall be smooth, plasticized uniformly, free of loop knot, and the section shall be neat without cracks	Meet the requirements
		3.1.2	The pump tube shall be translucent, the inner and outer surfaces shall be smooth, free of transverse or longitudinal cracks, free of impurity, and the section shall be neat and without cracks	Meet the requirements
		3.1.3	The connector shall be transparent, the inner and outer surfaces of the connector shall be smooth, free of impurity or burr, and the section shall be neat without cracks.	Meet the requirements
		3.1.4	Each terminal of the tube shall have a protective cap to keep the inner surface of the tube sterile. The protective cap shall not fall off naturally and shall be easy to dismantle.	Meet the requirements
		3.1.5	The arteriovenous tubes shall have obvious color markings at the ends, red for arterial tube and blue for venous tube.	Meet the requirements
2	Structural tightness	3.2.1	The hemodialysis tube shall be able to withstand 1.5 times the maximum positive pressure specified by the manufacturer and 1.5 times the maximum negative pressure specified by the manufacturer. If the 1.5 times negative pressure exceeds 93.3kPa (700mmHg), 93.3kPa (700mmHg) shall be applied.	Meet the requirements
	Hemodialysis connector	3.2.2.1	Unless it is designed as a complete system with the hemodialysis tube, the size of the connector connecting the hemodialysis device, hemodialysis filter or hemofiltration device shall be as shown in Figure 1.	Meet the requirements
		3.2.2.2	The connection between the connector and the supporting device shall be leak-free	Meet the requirements
	Connector connecting the blood channel device	3.2.3	There shall be no leakage between the connector connecting the blood channel device and the supporting device	Meet the requirements
	Connector connecting the auxiliary component	3.2.4	All parts of the hemodialysis tube scheduled to be used with various separate auxiliary components (e.g. heparin tube, pressure sensor tube, drug injection tube, and level adjustment tube) shall be leak-free in connection with the supporting devices.	Meet the requirements
	Color code	3.2.5	The terminal of the arterial blood line connected to the patient shall be marked in red, and the terminal of the venous blood line connected to the patient shall be marked in blue. The color code should be clearly marked within 100rmn at the terminal of the blood line.	Meet the requirements
	Sampling port	3.2.6	There shall be no leakage from the puncture sampling port. The design of the puncture element shall minimize the risk of injury caused by the needle penetrating the tube.	Meet the requirements
	Blood volume	3.2.7	The blood volume range of the hemodialysis tube shall meet the regulations of the manufacturer. The blood chamber volume tolerance is ±10% (specification: OCI-BD-D-A blood chamber volume: 160ml), (specification: OCI-BD-S-A blood chamber volume: 130ml), (specification: OCI-BD-S-B blood chamber volume: 125ml)	Meet the requirements
	Bubble trap pre-filled level	3.2.8	Correct operation of the monitoring system requires the use of the bubble trap pre-filled level recommended by the manufacturer. The pre-filled level shall be the lower edge line of the pot cover and the pot body, and shall be indicated in the instructions for use.	Meet the requirements
	Sensor protector	3.2.9	The sensor protector shall be able to withstand 1.5 times the maximum positive pressure (500mmHg) and still maintain its safety and leakage-free. The surface of the machine end of the sensor protector shall be transparent, and blood contamination can be visually checked during use	Meet the requirements
	Pump tube performance	3.2.10	Within the predetermined inlet pressure range of 0～33.3kPa (0～250mmHg), the relative deviation offlow rate shall not exceed 10%.	Meet the requirements
	Main tube and pump tube	3.2.11	The critical dimension, uniformity, and bending resistance shall meet the requirements	Meet the requirements
	Filter	3.2.12	The critical dimension shall meet the requirements.	Meet the requirements

	Blood flow rate	3.2.13	The relative deviation between the actual flow rate and the displayed flow rate shall not exceed 10%.	Meet the requirements
	Hemodialysis connector cap	3.2.14	The dimension shall meet the requirements, and the hemodialysis connector cap shall not fall off vertically, but can be dismantled with slight force.	Meet the requirements
	Wing type locking connector cap	3.2.15	The dimension shall meet the requirements, and the wing type locking connector cap shall not fall off vertically, but can be dismantled with slight force.	Meet the requirements
	Slip connector	3.2.16	The dimension shall meet the requirements	Meet the requirements
	Needle for inserting bottle	3.2.17	It shall be able to pierce through the stopper of the liquid container that has not been punctured, and it is not easy to produce chips, and the dimension shall meet the requirements.	Meet the requirements
	Interconnected connector	3.2.18	The interconnected connector and the Luer connector shall be firmly connected, and shall not leak under 1.5 times the maximum positive pressure (500mmHg), and shall be easy to dismantle, and the dimension shall meet the requirements.	Meet the requirements
3	Blood line compliance	3.3	The hemodialysis tube can be clamped and closed	Meet the requirements
4	Particulate pollution	3.4	The hemodialysis tube shall be clean. The number of particulates of 15- 25μm on the surface area per square centimeter shall not exceed 1, and the number of particulates of > 25μm shall not exceed 0.5.	0.46 0.03
5	Reducing substances	3.5.1	The volume difference of potassium permanganate solution [c ($KMn0_4$) = 0.002 mol/L] consumed by the 20 mL test solution and the blank control solution of the same batch shall not exceed 2.0mL.	0.20
	Heavy metal	3.5.2	When determined by the colorimetric method, the color of the test solution shall not be darker than that of the standard control solution at the mass concentration ρ (Pb^{2-}) = 1 μg/mL.	Meet the requirements
	pH value	3.5.3	The difference of pH value of the test solution and the blank control solution of the same batch shall not exceed 1.5.	0.36 0.43
	Residue on evaporation	3.5.4	The total residue on evaporation of 50 mL test solution shall not exceed 2 mg.	0.2mg 0.2mg
	Ultraviolet absorbance	2.5.5	The absorbance of the test solution shall not exceed 0.1.	0.032 0.036
	Color	3.5.6	The test solution shall be colorless and transparent.	Meet the requirements
6	Sterility	3.6.1	The hemodialysis tube shall be sterilized in a confirmed Gamma sterilization process.	Meet the requirements
	Pyrogen	3.6.2	There shall be no pyrogen when using the pyrogen test method. Endotoxin shall be less than 20EU/PCS when using the bacterial endotoxin test method.	Meet the requirements
Conclusion: upon testing in accordance with the SOP for Hemodialysis Blood Tubing Sets, the results meet the requirements.				

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