



CERTIFICATE OF ANALYSIS

PRODUCT NAME		Polyethersulfone Hollow Fiber Hemodialyzer				
MODEL		OCI-HD180	BATCH NO	251121	STERILE BATCH NO	2511030
PRODUCTION DATE		2025.11.08	EXPIRY DATE	2028.11.07	TOTAL QUANTITY	4416
SAMPLING DATE		2025.11.18	REPORT DATE	2025.11.21	REPORT NO	CA25111808
INSPECTION STANDARD		1. The testing method is in accordance with ISO 8637 requirements; 2. The aseptic testing operation is in accordance with ISO 11737-2 requirements.				
SN	TEST PROGRAM	STANDARD REQUEST		RESULTS	CONCLUSION	
1	Effective area	≥90% of nominal area (≥0.99 m²).		Meet the requirement	Pass	
2	Blood volume	105±10% mL		Meet the requirement	Pass	
3	Structure tightness	The product's structure tightness should be test by this condition: Positive pressure: 100 kPa(750 mmHg) Negative pressure: -93.3 kPa(700 mmHg) Under these pressures, the products should have no leakage.		No leakage	Pass	
4	Blood chamber tightness	Test under 100kPa, that is 1.5 times of highest TMP(500mmHg), the blood chamber should have no leakage.		No leakage	Pass	
5	Blood port cap connector	Blood port cap connector should meet the standard in ISO 8637.		Meet the requirement	Pass	
6	Dialysate port cap connector	Dialysate port cap connector should meet the standard in ISO 8637.		Meet the requirement	Pass	
7	Particulate	The hemodialyzer's inside should be clean. Use eluent to wash the product (100mL per/m² effective filtration area), the particulate between 15µm and 25µm should ≤200, particulate larger than 25µm should ≤100.		61 1	Pass	
8	Temperature range	The hemodialyzer will not break or deformation in the temperature range of 0~50 °C		Meet the requirement	Pass	
9	Reducing substances	The volume difference KMnO ₄ [c(KMnO ₄)=0.002 mol/L] consumed between sample and blank control ≤ 2.0 mL.		0.26	Pass	
10	Metal ion	In the hemodialyzer's extract solution, the total content of Ba, Cr, Cu, Pb and Sn≤1mg/L. And the content of Cd should less than 0.1mg/L.		Ba≤1mg/L, Cr≤1mg/L, Cu≤1mg/L, Pb≤1mg/L, Sn≤1mg/L, Cd< 0.1mg/L	Pass	
11	pH value	Sample and control's pH value difference ≤1.5		0.20 0.35	Pass	
12	Residue on evaporation	Residue on evaporation ≤2 mg		0.5mg 0.3mg	Pass	
13	UV Absorbance	Sample liquid's UV absorbance ≤0.1		0.043 0.049	Pass	
14	DMAC residue	DMAC residue should ≤50 mg/L.		DMAC≤50 mg/L	Pass	
15	Sterility	The products should be sterilized by affirmed effective sterilization method to ensure its sterility.		Sterile	Pass	
16	Pyrogen	When test pyrogen, the products should have no pyrogen; When test bacterial endotoxin, the bacterial endotoxin should <20 EU/sample.		Meet the requirement	Pass	
18	Ultrafiltration Rate (mL/kPa·h) Tolerance: ±20%	Blood flow 200mL/min		TMP 50 mmHg	320 mL/Kpa.h	Pass
				TMP 250 mmHg	170mL/Kpa.h	
				TMP 500 mmHg	95mL/Kpa.h	
		Blood flow 400mL/min		TMP 50 mmHg	370mL/Kpa.h	Pass
				TMP 250 mmHg	220mL/Kpa.h	
				TMP 500 mmHg	130mL/Kpa.h	
19	Carbamide Clearance rate (mL/min) O _F =0	Q _D =500mL/min	Q _b =200ml/min	193	Meet the requirement	Pass

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	mL/min; Tolerance: ±20%					
	Creatinine Clearance rate (mL/min) $Q_F=0$ mL/min; Tolerance: ±20%	$Q_D=500\text{mL/min}$	$Q_b=200\text{mL/min}$	197	Meet the requirement	Pass
	Phosphate Clearance rate (mL/min) $Q_F=0$ mL/min; Tolerance: ±20%	$Q_D=500\text{mL/min}$	$Q_b=200\text{mL/min}$	192	Meet the requirement	Pass
	VB ₁₂ Clearance rate (mL/min) $Q_F=0$ mL/min; Tolerance: ±20%	$Q_D=500\text{mL/min}$	$Q_b=200\text{mL/min}$	186	Meet the requirement	Pass
20	Pressure drop Tolerance: ±20%	$Q_B=200\text{mL/min}$ Pressure drop(kPa): ≤ 8 $Q_B=300\text{mL/min}$ Pressure drop(kPa): ≤ 12 $Q_B=400\text{mL/min}$ Pressure drop(kPa): ≤ 18			Meet the requirement	Pass

Results:

- All the above goods are manufactured as per the international standards.
- The batch is manufactured according to goods manufacturing practices.

INSPECTOR	Wang Hongmin	AUDITOR	Long Jun	APPROVER	Zhu Yinhao
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