



CERTIFICATE OF ANALYSIS

PRODUCT NAME		Polyethersulfone Hollow Fiber Hemodialyzer				
MODEL		OCI-HD200	BATCH NO	251129	STERILE BATCH NO	2511036
PRODUCTION DATE		2025.11.10	EXPIRY DATE	2028.11.09	TOTAL QUANTITY	1104
SAMPLING DATE		2025.11.18	REPORT DATE	2025.11.21	REPORT NO	CA25111811
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	115 ± 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.		49 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.		0.25	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		0.59 0.43	Pass	
12	Residue on evaporation	Residue on evaporation ≤2 mg		0.3mg 0.4mg	Pass	
13	UV Absorbance	Sample liquid's UV absorbance ≤0.1		0.047 0.048	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	341 mL/Kpa.h	Pass
				TMP 250 mmHg	180mL/Kpa.h	
				TMP 500 mmHg	99mL/Kpa.h	
		Blood flow 400mL/min		TMP 50 mmHg	393mL/Kpa.h	Pass
				TMP 250 mmHg	230mL/Kpa.h	
TMP 500 mmHg	146mL/Kpa.h					
19	Carbamide Clearance rate (mL/min) O _F =0	Q _D =500mL/min	Q _b =200ml/min	195	Meet the requirement	Pass

CHENGDU OCI MEDICAL DEVICES CO., LTD

No.2401, West Port Avenue, Southwest Airport Economic Development Zone,
Shuangliu District, Chengdu, Sichuan Province, China.
Tel.: +86-28-67085899

Fax: +86-28-67085880



	mL/min; Tolerance: ±20%					
	Creatinine Clearance rate (mL/min) $Q_F=0$ mL/min; Tolerance: ±20%	$Q_D=500\text{mL/min}$	$Q_b=200\text{mL/min}$	192	Meet the requirement	Pass
	Phosphate Clearance rate (mL/min) $Q_F=0$ mL/min; Tolerance: ±20%	$Q_D=500\text{mL/min}$	$Q_b=200\text{mL/min}$	189	Meet the requirement	Pass
	VB ₁₂ Clearance rate (mL/min) $Q_F=0$ mL/min; Tolerance: ±20%	$Q_D=500\text{mL/min}$	$Q_b=200\text{mL/min}$	160	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 Yunhao
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