CHENGDU OCI MEDICAL DEVICES CO., LTD
No.2401, West Port **Avenue**, Southwest Airport Economic Development Zone,
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CERTIFICATE OF ANALYSIS

PRODUCT NAME		Polyethersulfone Hollow Fiber Hemodialyzer				
MODEL		OCI-HD180	**BATCH NO**	260353	**STERILE BATCH NO**	2603063
PRODUCTION DATE		2026.03.21	**EXPIRY DATE**	2029.03.20	**TOTAL QUANTITY**	3840
SAMPLING DATE		2026.03.28	**REPORT DATE**	2026.04.01	**REPORT NO**	CA26032801
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 m^2).	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/m^2 effective filtration area), the particulate between 15μm and 25μm should ≤200, particulate larger than 25μm should ≤100.	50 3	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.	0.16	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	0.45 0.39	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	0.043 0.042	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
		Blood flow 200mL/min, TMP 250 mmHg	170mL/Kpa.h	
		Blood flow 200mL/min, TMP 500 mmHg	95mL/Kpa.h	
		Blood flow 400mL/min, TMP 50 mmHg	370mL/Kpa.h	Pass
		Blood flow 400mL/min, TMP 250 mmHg	220mL/Kpa.h	
		Blood flow 400mL/min, TMP 500 mmHg	130mL/Kpa.h	
19	Carbamide Clearance rate (mL/min) Q_F=0	Q_D=500mL/min, Qb=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=500mL/min	Qb=200ml/min	188	Meet the requirement	Pass
	Phosphate Clearance rate (mL/min) Q_F=0 mL/min; Tolerance: ±20%	Q_D=500mL/min	Qb=200ml/min	186	Meet the requirement	Pass
	VB_{12} Clearance rate (mL/min) Q_F=0 mL/min; Tolerance: ±20%	Q_D=500mL/min	Qb=200ml/min	157	Meet the requirement	Pass
20	Pressure drop Tolerance: ±20%	Q_B=200ml/min Pressure drop(kPa): ≤ 8 Q_B=300ml/min Pressure drop(kPa): ≤ 12 Q_B=400ml/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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