



HYPHEN BioMed
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France



ANALYSIS CERTIFICATE

BIOPHEN™ Anti-IIa (2 stages Heparin assay) - #220005

Lot : FE4133

QC Release : ...

Expiration date : 2028-05-19

19 JAN. 2026

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FE4133	2028-05-19
R2 : Thrombin	2 vials	30	FE4133	2028-05-26
R3 : Substrate	2 vials	30	FE4133	2028-05-23

825

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Lot : FE4133

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Analytical data				Specifications
1. ATIII (h)				
a. Lot homogeneity (A405 for 0 IU/ml heparin)				
N=	35	Mean (A405) :	2.894	
		CV :	1.0 %	≤ 5 %
b. AT content per vial (anti-Xa activity chromogenic assay on raw material)				
			1.4 IU	≥ 1.2 IU
c. Indicative AT content per vial (A280nm/Lowry on raw material)				
			132 µg	
d. SDS PAGE (on raw material)				1 major band of about 58,000 Da
		1 major band of about 58 000 Da		
e. Absence of heparin				Absence
Absence				
2. Thrombin (h)				
a. Lot homogeneity (A405 for 0 IU/ml heparin)				
N=	35	Mean (A405) :	2.870	
		CV :	0.9 %	≤ 5 %
b. SDS PAGE (5% acrylamide) (on raw material)				1 major band of about 35,000 Da
		1 major band of about 35 000 Da		
c. Indicative IIa content per vial (Lowry on raw material)				
			51.1 µg	
d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa)				
			91 NIH (or IU)	
e. Indicative specific chromogenic activity (on raw material) (chromogenic assay using CS-01(38))				
			2.26 nkats/µg	
3. Thrombin substrate				
a. Blank value				N≥5
N=	5	Mean (A405) :	0.126	A405 ≤ 0.30
b. Lot homogeneity (A405 for 0 IU/ml heparin)				
N=	35	Mean (A405) :	2.883	
		CV :	2.5 %	≤ 5 %
c. Indicative content per vial (raw material)				
			6.25 mg (about 11.25 µmol)	
d. HPLC analysis purity grade (raw material)				
			98 %	≥ 95%
e. Experimental molecular weight (raw material)				
			552 Da	553 ± 5 Da

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5. Assay reactivity (in the tested dilution, CS-series)								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$
IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R^2	
A405 UFH purified	1.473	1.243	1.057	0.728	0.501	0.411	0.992	
A405LMWH purified	1.357	1.160	0.968	0.608	0.355	0.223	0.996	
6. UFH Detection threshold (concentration in the tested dilution, CS-series)								≤ 0.005 IU/mL
In Purified solution < 0.001 IU/mL								
7. Stability of reconstituted reagents (purified milieu, CS-series) Reagents tested after 15 days at 2-8°C, or 4 days at RT (18-25°C) or Frozen $\leq -20^\circ\text{C}$ A405 values for UFH								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$ $\Delta A405 (0 \text{ IU/mL}) \leq 10\%$ between fresh and stored $A405 (\text{Free pNA}) \leq 0.30$
UFH IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R^2	
Freshly restored	1.310	1.080	0.884	0.573	0.378	0.262	0.998	
15 days at 2-8°C	1.352	1.098	0.907	0.601	0.410	0.294	0.998	
7 days at RT	1.334	1.126	0.943	0.663	0.477	0.346	1.000	
Frozen $\leq -20^\circ\text{C}$	1.388	1.132	0.935	0.604	0.394	0.267	1.000	
Comments :								☒ PASSED IN COMPLIANCE

Date :

QC Manager :

Quality Control Approval

19 JAN. 2026

S. LECOURT