



HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France



ANALYSIS CERTIFICATE

BIOPHEN HEPARIN Anti IIa (kinetics) - #221020

Lot : FD050612

QC Release : 19 AVR. 2024

Expiration date: 2026-08-21

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : Human Antithrombin	2 vials	30	FD050612	2026-08-21
R2 : Thrombin substrate	2 vials	30	FD050612	2026-08-25
R3 : Human Thrombin	2 vials	30	FD050612	2026-09-11
R4 : Reaction buffer	2 vials	30	FD050612	2026-09-04

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Analytical data	Specifications
<p>1. AT</p> <p>a. Reproducibility for AT concentration (AT chromogenic assay): N: 5 AT : 225 % CV: 0.5 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay) 2.25 IU</p> <p>c. Indicative AT content per vial (A280nm/Lowry on raw material) 1000 µg</p> <p>d. SDS PAGE (on raw material) 1 major band of about 58,000 Da</p> <p>e. Absence of heparin</p>	<p>N ≥ 5 ≥ 100% ≤ 5 % ≥ 1 IU 1 major band of about 58,000 Da Absence</p>
<p>2. Thrombin substrate (CS-01(38))</p> <p>a. Blank value (N ≥ 5) Mean (A405) : 0.216</p> <p>b. Reproducibility for U IU/ml Heparin: N: 5 Mean (A405): 1.896 CV: 2.4 %</p> <p>c. Indicative content per vial (raw material) 25 mg (about 33.9 µmol)</p> <p>d. HPLC analysis purity grade (raw material) 99 %</p> <p>e. Experimental molecular weight (raw material) 552.6 Da</p>	<p>A405 ≤ 0.30 N ≥ 5 indicative ≥ 1.80 ≤ 5 % ≥ 95% 553 ± 5 Da</p>
<p>3. Thrombin</p> <p>a. Reproducibility for 0 IU/ml Heparin: N: 5 Mean (A405) : 1.831 CV: 2.1 %</p> <p>b. SDS PAGE (5% acrylamide) (on raw material) 1 major band of about 35,000 Da</p> <p>c. Indicative IIa content per vial (Lowry on raw material) 10.3 µg</p> <p>d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa) 21.9 NIH (or IU)</p> <p>e. Indicative chromogenic activity per vial (on raw material) (chromogenic assay using CS-01(38)) 56 nkats</p>	<p>N ≥ 5 indicative ≥ 1.80 ≤ 5 % 1 major band of about 35,000 Da</p>
<p>4. Reaction buffer</p> <p>Volume: 21 ml pH: 8.37</p> <p>Aspect: <input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p>	<p>≥ 20 ml [8.30 - 8.50] Clear - Transparent</p>

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Analytical data							Specifications
5. Assay reactivity							Δ A405 (0-6IU/ml) \geq 1.00 $R^2 \geq 0.98$ $R^2 \geq 0.98$
a. Manual method: 5 minutes							
UFH UI/ml	0.0	0.5	1.0	2.0	4.0	6.0	
A405	2.003	1.813	1.621	1.298	0.931	0.683	
R^2 0.995							
b. Automated method : Instrument: STAR							
UFH UI/ml	0.0	0.5	1.0	2.0	4.0	6.0	
A405	1.687	1.528	1.380	1.080	0.772	0.551	
R^2 0.995							
c. Detection threshold							
Instrument: STAR							
A405 (0 UI/ml) - 3SD = 1.672							
Detection threshold: <0.20 UI/ml							≤ 0.20 UI/ml
6. Stability of reconstituted reagents							$R^2 \geq 0.98$ Δ A405 (test tube) (0 to 6 IU/ml) ≥ 1.00 Δ A405 between trials $\leq 10\%$
Reagents tested after 15 days at 2-8°C, or 3 days at RT or Frozen/thawed							
A405 values							
UFH UI/ml	0.0	0.5	1.0	2.0	4.0	6.0	
Freshly restored	1.668	1.516	1.382	1.128	0.786	0.598	
15 days at 2-8°C	1.751	1.592	1.429	1.159	0.804	0.602	
3 days at RT	1.743	1.586	1.420	1.140	0.795	0.602	
Frozen & Thawed	1.793	1.615	1.427	1.142	0.765	0.572	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
Quality Control Approval	

Date :

19 AVR. 2024
 S. LECOURT

QC Manager :