



HYPHEN BioMed
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 France



ANALYSIS CERTIFICATE

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

Lot : FA037117

QC Release : 2021-03-10

Expiration date : 2023-07-29

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FA037117	2023-08-04
R2 : Thrombin	2 vials	30	FA037117	2023-08-07
R3 : Substrate	2 vials	30	FA037117	2023-07-29

SOS

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Analytical data	Specifications
<p>1. ATIII (h)</p> <p>a. Lot homogeneity (A405 for 0 IU/ml heparin)</p> <p>N= 35 Mean (A405) : 2.895 CV : 1.7 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay on raw material)</p> <p style="text-align: right;">1.72 IU</p> <p>c. Indicative AT content per vial (A280nm/Lowry on raw material)</p> <p style="text-align: right;">≈190 µg</p> <p>d. SDS PAGE (on raw material)</p> <p style="text-align: right;">1 major band of about 58,000 Da</p> <p>e. Absence of heparin</p> <p style="text-align: center;">Absence</p>	<p>≤ 5 %</p> <p>≥ 1.2 IU</p> <p>1 major band of about 58,000 Da</p> <p>Absence</p>
<p>2. Thrombin (h)</p> <p>a. Lot homogeneity (A405 for 0 IU/ml heparin)</p> <p>N=35 Mean (A405) : 2.904 CV : 1.3 %</p> <p>b. SDS PAGE (5% acrylamide) (on raw material)</p> <p style="text-align: right;">1 major band of about 35,000 Da</p> <p>c. Indicative IIa content per vial (Lowry on raw material)</p> <p style="text-align: right;">≈ 42.4 µg</p> <p>d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa)</p> <p style="text-align: right;">≈ 110 NIH (or IU)</p> <p>e. Indicative specific chromogenic activity (on raw material) (chromogenic assay using CS-01(38))</p> <p style="text-align: right;">5.98 nkats/µg</p>	<p>≤ 5 %</p> <p>1 major band of about 35,000 Da</p>
<p>3. Thrombin substrate</p> <p>a. Blank value</p> <p>N= 5 Mean (A405) : 0.127</p> <p>b. Lot homogeneity (A405 for 0 IU/ml heparin)</p> <p>N= 35 Mean (A405) : 2.895 CV : 1.3 %</p> <p>c. Indicative content per vial (raw material)</p> <p style="text-align: right;">6.25 mg (about 11.3 µmol)</p> <p>d. HPLC analysis purity grade (raw material)</p> <p style="text-align: right;">98 %</p> <p>e. Experimental molecular weight (raw material)</p> <p style="text-align: right;">553 Da</p>	<p>N≥5 A405 ≤ 0.30</p> <p>≤ 5 %</p> <p>≥ 95%</p> <p>553 ± 5 Da</p>

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5. <u>Assay reactivity (in the tested dilution, CS-series)</u>								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$
IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R ²	
A405 UFH purified	1.560	1.240	1.015	0.659	0.441	0.306	0.998	
A405LMWH purified	1.549	1.156	0.850	0.410	0.228	0.141	0.996	

6. <u>UFH Detection threshold (concentration in the tested dilution, CS-series)</u>								≤ 0.005 IU/mL
In Purified solution		< 0.005 IU/mL						

7. <u>Stability of reconstituted reagents (purified milieu, CS-series)</u>								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$ $\Delta A405 (0 \text{ IU/mL}) \leq 10\%$ between fresh and stored A405 (Free pNA) ≤ 0.30	
Reagents tested after 15 days at 2-8°C, or 4 days at RT (18-25°C) or Frozen ≤ -20°C									
A405 values for UFH									
UFH IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R ²		A405 (Free pNA)
Freshly restored	1.553	1.047	0.816	0.443	0.272	0.178	0.994		0.125
15 days at 2-8°C	1.583	1.095	0.867	0.490	0.300	0.207	0.992	0.127	
4 days at RT	1.556	1.095	0.865	0.496	0.300	0.214	0.992	0.128	
Frozen ≤ -20°C	1.489	0.988	0.764	0.402	0.229	0.144	0.996	0.128	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2021-03-10

QC Manager : S.LECOURT

