HYPHEN BioMed
ZAC Neuville Université - 155 rue d'Eragny
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Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN Anti Xa (2 Stage) - #221010 **Lot : F1700791**

QC Release : 01/08/2017 **Expiration date : 2019-08-19**

Components	Qty	Exp. (months)	LOT #	EXP.Date
R1 : Human Antithrombin	2 vials	30	F171100232	2019-08-19
R2 : Bovine FXa	2 vials	30	F171100232	2019-08-26
R3 : Substrate	2 vials	30	F171100232	2019-08-24
R4 : Reaction buffer	4 vials	30	F171200766	2019-12-27

Reo.

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Analytical data	Specifications
1. AT	
a. Reproducibility (A405 for 0 IU/ml heparin)	
N : 25	
Mean (A405) : 2,000	
CV : 1,3 %	≤ 5 %
b. AT content per vial (anti-Xa activity chromogenic assay)	
6,95 IU	≥ 4.75 IU
c. Indicative AT content per vial (A280/Lowry on raw material)	
695 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 (on raw material)	Absence
Absence	
2. Substrate	
a. Blank value	N ≥ 5
Mean (A405) : 0,077	A405 ≤ 0.30
b. Reproducibility (A405 for 0 IU/ml heparin)	
N : 25	
Mean (A405) : 1,996	
CV : 1,1 %	≤ 5 %
c. Indicative content per vial (raw material)	
5 mg (about 7,83 µmol)	
d. HPLC analysis purity grade (raw material)	
98 %	≥ 95%
e. Experimental molecular weight (raw material)	
641,5 Da	641.7 ± 5 Da
3. FXa	
a. Reproducibility (A405 for 0 IU/ml heparin)	
N : 20	
Mean (A405) : 1,999	
CV : 1,0 %	≤ 5 %
b. SDS PAGE (4-12% acrylamide) (FX zymogen for raw material)	1 major band of about 55,000 Da
1 major band of about 55 000 Da	
c. Indicative FXa content per vial (Lowry, from zymogen raw material)	
58 µg/vial	
d. Chromogenic activity on Xa substrate (10µg/ml) (raw material)	
A405 with RVV : 1,145	ΔA405 <10%
A405 without RVV : 1,135	
e. Indicative chromogenic activity on Xa substrate (CS-11(22)) (raw material)	
162,4 nkats / vial	
4. Reaction buffer (N ≥ 3)	
Volume : >25 ml	≥ 25 ml
pH 8,47	8.40 ± 0.20
Aspect: ☑ Clear ☑ Transparent	Clear - Transparent

Ico

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Analytical data	Specifications

5. Assay reactivity

STAR method (concentration in the tested dilution)

A405	UI/ml	0.0	0.025	0.050	0.075	0.100	R^2
Plasma	UFH	2,555	2,104	1,716	1,358	1,038	0,996
	LMWH	2,555	2,304	1,947	1,725	1,425	0,996
Purified milieu	UFH	2,661	2,112	1,655	1,282	0,966	0,998
	LMWH	2,664	2,350	2,027	1,719	1,474	0,998

Specifications: $R^2 \geq 0.98$

6. Detection threshold (concentration in the tested dilution)

In Plasma <0,01 IU/ml

In Purified solution <0,01 IU/ml

Specifications: ≤ 0.01 IU/ml

7. Stability of reconstituted reagents

Reagents tested after 7 days at 2-8°C, or 7 days at RT (18-25°C) or Frozen/thawed at ≈ -20°C

A405 values for UFH

IU/ml	0.0	0.025	0.050	0.075	0.100	R^2
Freshly restored	2,087	1,653	1,064	0,606	0,367	0,983
7 days at 2-8°C	2,098	1,675	1,054	0,623	0,363	0,983
7 days at RT (18-25°C)	2,097	1,627	1,035	0,588	0,341	0,983
Frozen & Thawed ≈ -20°C	2,115	1,668	1,060	0,597	0,355	0,983

Specifications: $R^2 \geq 0.98$
ΔA405(0UI/ml)between trials ≤10%

Comments :

☑ **PASSED IN COMPLIANCE**

Date 01/08/2017 **QC Manager : S. LECOURT**