



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN HEPARIN 6

**Product Code:** 221006

**Lot No.:** FB05549V

**Expiration date:** 2024-09-14

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FB0554BF9V	2024-09-14
R2 : Bovine FXa	4 vials	FB0554BG9V	2024-10-05

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> <li>• For a same A405 (UFH/LMWH):</li> <li>MV = TV <math>\pm</math>0.05 IU/ml for conc. <math>\leq</math> 0.50 IU/ml</li> <li>MV = TV <math>\pm</math>0.10 IU/ml for conc. <math>&gt;</math> 0.50 IU/ml</li> <li>• <math>R^2 \geq 0.98</math></li> </ul>	PASS
DETECTION THRESHOLD	$\leq 0.05$ IU/mL	$< 0.01$ IU/mL

### Calibration Curve for information

Conc. LMWH	0	0.45	0.92	1.36	1.80
OD STAR	1.501	1.061	0.769	0.566	0.448
OD CS	0.687	0.454	0.309	0.215	0.154

	Acceptance Range	MV
C3	[ 0.70 - 0.90 ]	0.76
C4	[ 1.01 -1.37 ]	1.16

MV = Measured value

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval: 2022-05-31

Quality Control Manager: S.LECOURT