



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN 6

Product Code : 221006

Lot No. : FE3351 /FE3358

Expiration date : 2028-02-12

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FE3351 / FE3358	2028-02-12
R2 : Bovine FXa	4 vials	FE3351 / FE3358	2028-03-12

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	- For a same A405 (UFH/LMWH): - MV = TV $\pm$0.05 IU/ml for conc. $\leq$ 0.50 IU/ml - MV = TV $\pm$0.10 IU/ml for conc. > 0.50 IU/ml $R^2 \geq 0.98$	PASS PASS >0.99

Calibration Curve for information

Conc. LMWH	0.00	0.44	0.93	1.39	1.81
OD STAR	1.580	1.046	0.707	0.480	0.315
OD CS	0.683	0.452	0.306	0.215	0.154

	Acceptance Range	MV
C3	[0.68 - 0.88]	0.76
C4	[1.10 - 1.30]	1.17

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 :

Quality Control Manager :

Quality Control Approval

09 OCT. 2025
S. LECOURT

