



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN 6

Product Code : 221006

Lot No. : FC2266GY

Expiration date : 2026-04-28

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FC2266BFGY	2026-04-28
R2 : Bovine FXa	4 vials	FC2266BGGY	2026-05-03

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> For a same A405 (UFH/LMWH): MV = TV \pm0.05 IU/ml for conc. \leq 0.50 IU/ml MV = TV \pm0.10 IU/ml for conc. $>$ 0.50 IU/ml $R^2 \geq 0.98$ 	PASS PASS >0.99
DETECTION THRESHOLD	≤ 0.05 IU/ml	<0.01 IU/mL

Calibration Curve for information

Conc. LMWH	0.00	0.44	0.93	1.39	1.81
OD STAR	1.519	1.036	0.697	0.443	0.310
OD CS					

	Acceptance Range	MV
C3	[0.68 - 0.88]	0.76
C4	[1.07 - 1.27]	1.20

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 Approval

Quality Control Manager :

07 DEC. 2023

S. LECOURT