



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN 6

Product Code : 221006

Lot No. : F2001366

Expiration date : 2023-04-01

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	F201501366	2023-04-01
R2 : Bovine FXa	4 vials	F201501366	2023-04-08

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> 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
DETECTION THRESHOLD	≤ 0.05 IU/ml	< 0.05 IU/ml

Calibration Curve for information

Conc. LMWH	0	0.45	0.92	1.36	1.8
OD STAR	1.453	0.974	0.664	0.451	0.311
OD CS	0.671	0.449	0.305	0.215	0.149

	Acceptance Range	MV
C3	[0.69 - 0.93]	0.78
C4	[1.10 - 1.40]	1.24

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 : 2020-11-05

Quality Control Manager : **S.LECOURT**

