



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221011

Lot No. : FF1333W7 / FF1349

Expiration date : 2027-12-14

Components	Quantity	Lot	Expiration Date
R1 : Sxa-11 substrate	4 vials	FF1333BHW7 / FF1349	2028-04-28
R2 : Bovine FXa	4 vials	FF1333BIW7 / FF1349	2027-12-14

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
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON CS	- 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	1.795	1.267	0.905	0.664	0.489
OD CS	0.758	0.493	0.326	0.222	0.153

	Acceptance Range	MV
C3	[0.63 - 0.83]	0.73
C4	[1.10 - 1.30]	1.22

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 :

28 JUL. 2026

S.MONEUS

