



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ Heparin LRT

Product Code : 221015

Lot No. : F2000403

Expiration date : 2021-09-28

Components	Quantity	Lot	Expiration Date
R1 : Sxa-11 substrate	4 vials	F204300403	2021-09-28
R2 : Bovine FXa	4 vials	F204300403	2021-09-28

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 • R² \geq 0.98 	PASS
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON CS	<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 • R² \geq 0.98 	PASS
DETECTION THRESHOLD	\leq 0.05 IU/ml	$<$ 0.01 IU/ml

Calibration Curve for information

Conc. LMWH	0	0.5	1.0	1.50	1.95
OD STAR	1.743	1.198	0.859	0.617	0.447
OD CS	0.747	0.467	0.302	0.200	0.141

	Acceptance Range	MV (STAR)
C3	[0.68 - 0.92]	0.84
C4	[1.06 - 1.44]	1.28

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: 2020-04-24

Quality Control Manager: S. LECOURT