



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ Heparin LRT

Product Code : 221015

Lot No. : FA120974

Expiration date : 2022-12-27

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FA1209BH74	2022-12-27
R2 : Bovine FXa	4 vials	FA1209BI74	2022-12-27

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

						Acceptance Range	MV
Conc. LMWH	0	0.45	0.92	1.36	1.80	C3 [0.68 -0.92]	0.82
OD STAR	1.610	1.111	0.795	0.597	0.446	C4 [1.03 -1.39]	1.22
OD CS	0.710	0.458	0.303	0.209	0.146		

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 : 2021-07-20

Quality Control Manager : S.LECOURT


