



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221013

Lot No. : FC0049CP

Expiration date : 2024-07-09

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	3 vials	FC0049BHCP	2024-12-06
R2 : Bovine FXa	3 vials	FC0049BICP	2024-07-09

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	0.00	0.44	0.93	1.39	1.81	Acceptance Range	MV
OD STAR	1.684	1.161	0.837	0.601	0.443	[0.66 - 0.90]	0.80
OD CS	0.720	0.468	0.306	0.206	0.140	[1.05 - 1.43]	1.21

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 : 2023-02-22

Quality Control Manager : **S.LECOURT**

