



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221011

Lot No. : FA06005Q

Expiration date : 2022-09-20

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FA0600BH5Q	2022-09-20
R2 : Bovine FXa	4 vials	FA0600BI5Q	2022-09-20

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	0.45	0.92	1.36	1.80
OD STAR	1.638	1.171	0.855	0.616	0.478
OD CS	0.716	0.474	0.318	0.216	0.145

	Acceptance Range	MV
C3	[0.64 - 0.86]	0.75
C4	[1.06 - 1.44]	1.26

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 : 2021-04-23

Quality Control Manager : S.LECOURT

