



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ Heparin LRT

Product Code : 221015

Lot No. : F2000792

Expiration date : 2021-12-14

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	F204600792	2021-12-14
R2 : Bovine FXa	4 vials	F204600792	2021-12-14

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 • R\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 • R\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	1.693	1.187	0.854	0.622	0.457
OD CS	0.739	0.484	0.322	0.221	0.157

	Acceptance Range	MV
C3	[0.70 - 0.90]	0.80
C4	[1.10 - 1.40]	1.25

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: 2020-07-16

Quality Control Manager: S. LECOURT

