



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ Heparin LRT

Product Code : 221015

Lot No. : F1800339-F1800409

Expiration date : 2019-09-11

Components	Quantity	Lot	Expiration Date
R1 : Sxa-11 substrate	4 vials	F182A00339-F182D00409	2019-09-11
R2 : Bovine FXa	4 vials	F182A00339-F182D00409	2019-09-11

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 R ² = 0,99
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 R ² = 0,99
DETECTION THRESHOLD	\leq 0.05 IU/ml	$<$ 0,01 IU/ml

Calibration Curve for information

Conc. LMWH	0	0.47	0.94	1.47	1.93
OD STAR	1.796	1.246	0.887	0.611	0.448
OD CS	0.798	0.508	0.328	0.204	0.141

	Acceptance Range	MV (STAR)
C3	[0,69 - 0,89]	0,79
C4	[1,03 - 1,39]	1,20

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 : 2018-04-24

Quality Control Manager :

M.PEYRAFITTE