



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ Heparin LRT

Product Code : 221015

Lot No. : F1801339

Expiration date : 2020-03-25

Components	Quantity	Lot	Expiration Date
R1 : Sxa-11 substrate	4 vials	F182W01339	2020-03-25
R2 : Bovine FXa	4 vials	F182W01339	2020-03-25

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> For a same A405 (UFH/LMWH): MV = TV ±0.05 IU/ml for conc. ≤ 0.50 IU/ml MV = TV ±0.10 IU/ml for conc. > 0.50 IU/ml • R² ≥ 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 ±0.05 IU/ml for conc. ≤ 0.50 IU/ml MV = TV ±0.10 IU/ml for conc. > 0.50 IU/ml • R² ≥ 0.98 	PASS R ² = 0.99
DETECTION THRESHOLD	≤ 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	1.653	1.149	0.813	0.573	0.411
OD CS	0.748	0.475	0.312	0.198	0.132

	Acceptance Range	MV (STAR)
C3	[0.66 - 0.90]	0.77
C4	[1.06 - 1.36]	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 : 2018-11-15

Quality Control Manager :

M.PEYRAFITTE

