

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COATEST LMW Heparin	PRODUCT # : 82136363
EXP. DATE: 2007-01	LOT # : N0347662
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 821363

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa (650-278)					
ACTIVITY	11	15	nkat/vial	11	PASS
STANDARD CURVE (r^2)	0.990	--	--	1.000	PASS
CONTROL RECOVERY	59.2	65.4	nkat/vial	63.5	PASS
RESIDUAL MOISTURE	0	5	%	1.9	PASS

B. S-2732 6 mg, FOR COATEST LMW HEPARIN (650-285)					
SUBSTRATE CONCENTRATION	5.70	6.30	mg/vial	5.84	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.01	PASS
RESIDUAL MOISTURE	0	5	%	0.6	PASS

C. LMW HEPARIN STANDARD (650-261)					
REGRESSION COEFFICIENT (r^2)	0.98	--	--	0.984	PASS
SLOPE	-0.400	-0.600	--	-0.409	PASS
INTERCEPT	-0.100	0.100	--	0.03	PASS
LMW HEPARIN CONTENT	95	105	IU/mL	102	PASS

D. BUFFER pH 8.4 CONC.(650-216), FOR COATEST LMW HEPARIN					
APPEARANCE	clear, colorless solution			PASS	PASS
pH @ 20 - 25°C	8.3	8.5	--	8.3	PASS

E. COATEST LMW HEPARIN/HEPARIN KIT					
SLOPE	-0.400	-0.600	--	-0.432	PASS
INTERCEPT	-0.100	0.100	--	-0.054	PASS
REGRESSION COEFFICIENT (r^2)	0.98	--	--	0.98	PASS

KIT COMPONENTS :

NAME	LOT NUMBER	EXP. DATE	VOLUME
FXa	N0247606	2007-02	1 ml (x 1)
S-2732, 6 mg	N0247506	2007-02	1 ml (x 1)
LMW HEPARIN CALIBRATOR	N0247316	2007-02	1 ml (x 1)
BUFFER pH 8.4	N0147003	2007-01	20 ml (x 1)

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY:

Raquel Bustamante

DATE: 03/09/04

APPROVAL SIGNATURE:

John Facciola

DATE: 03/09/04