CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation Laboratory

A Werfen Company

PRODUCT NAME:	COAMATIC HEPARIN					EXP DATE:	2021-03	
PRODUCT NUMBER:	NUMBER: 82339363			2				
LOT NUMBER:	_							
	\=====================================							
TEST DESCRIPTION		SPECIFIC	SPECIFICATIONS		RESULTS	DISPOSITION		
		MIN	MAX	UNITS		PASS/FAIL		
A. FACTOR Xa		7.9						
pH			8.1	pH	7.9	PASS		
ACTIVITY		31.5	38.5	nkat/vial	34.8		PASS	
ACTIVITY		31.3	30.5	TIKAD TICI	04.0			
STANDARD CURVE (²)		0.990	1.000		0.998	PASS		
STANDARD GORVE (I)	0.020							
CONTROL RECOVERY	66.0	73.0	nkat/vial	69.8	PASS			
						1		
					L			
B. S-2732, FOR COAMATIC	HEDADIN							
SUBSTRATE CONCENTRA	14.3	15.7	mg/vial	14.7	PASS			
SUBSTRATE GORGERTHATION		''."						
FREE p-NITROANILINE		0	0.5	mol %	0	PASS		
	- I MALLIEDADIN ON	TOD						
C. COAMATIC HEPARIN KI SLOPE	-0.351	-0.103		-0.195		PASS		
SLOPE		40.001	0.100	1				
r ²	0.985			0.996	PASS			
D. COAMATIC HEPARIN KI	T - UNFRACTIONATE	D HEPARIN ON TO	•					
SLOPE		-0,336	-0.114	-	-0.173	PASS		
				1		PASS		
r ²		0.985			0.997	P	ASS	
WE COMPONENTO								
KIT COMPONENTS:	NAME			LOT NUMBE	R	1	/OLUME	
				N0394317			1 mL	
COAMATIC HEPARIN FACTOR Xa COAMATIC HEPARIN S-2732			N0394319			2 mL		
COAW	ATIC HEPARIN 0-2702			7,000 707				
We hereby certify that the al	bove product(s):							
· have been manufactured a	nd tested according to t	he requirements of the	neir Manufac	turing and Qu	ality Control p	orocedures an	d have been foun	
to meet all conditions set for	th with these documents	s;	- Introduction of	OF made	.al			
meet all applicable require	ments of the 98/79/EC L	Directive according to	Which they	are CE marke	eu.			
		1/-	11-11	1			4-3-1	
	Maria Onlineas	11/10/1	Well	coney	DATE:	4/3/2019	4-0-1	
PREPARED BY:	Maria Oettinger PRINT	SIGNATURE	000	1	DATE.			
	PRINT	SIGNATORE	-	0				
TX1	TLE: QC Analyst III							
111	ILL. QUININGS III	Λ						
		70/1	9.47.5				11/2/19	
APPROVAL SIGNATURE:	D.Tencza	1. Wence	na		DATE:	4/3/2019	7/0/11	
	PRINT	SIGNATURE	7)				-T/: 10	

TITLE: Senior QC Analyst