

# ANALYSIS CERTIFICATE

**BIOPHEN EDOXABAN CONTROL LOW - #225401**

**Lot : F1701138**

**QC Release : 2017-11-06**

**Expiration date : 2020-03-24**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
CI : Control I	6 vials	30	F171101138	2020-03-24
CII : Control II	6 vials	30	F171101138	2020-03-24

*Handwritten signature*

# ANALYSIS CERTIFICATE

**BIOPHEN EDOXABAN CONTROL LOW - #225401**

**Lot : F1701138**

**QC Release : 2017-11-06**

**Expiration date : 2020-03-24**

Analytical data	Specifications
<b>1. <u>Within lot homogeneity (on N vials)</u></b>	
<b>Mean OD</b>	
N= 20                      CI: 1,383                      CV:                      0,7 %	CV(OD) ≤ 2%
N= 20                      CII: 1,158                      CV:                      0,5 %	CV(OD) ≤ 2%

<b>2. <u>Concentration and acceptance range</u></b>					<b>Target value:</b>  CI: 15 to 35 ng/mL  CII: 45 to 105 ng/mL
Controls	N series	[C] ng/mL	SD	Acceptance range (ng/mL)	
CI	9	27	1,30	17 - 37	
CII	9	77	1,82	62 - 92	

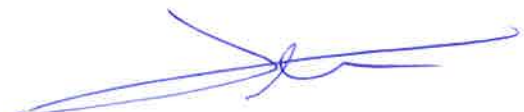
<b>3. <u>Aspect</u></b>			Slightly opalescent to clear  No coagulum  Stable solution
Slightly opalescent to clear	<input checked="" type="checkbox"/>		
No coagulum	<input checked="" type="checkbox"/>		
Stable solution	<input checked="" type="checkbox"/>		

<b>4. <u>Stability of reconstituted reagents</u></b>				<b><u>24h at RT (18-25°C) or 7 days at 2-8°C:</u></b>  Controls within  the acceptance range
	Temp.	CI ng/mL	CII ng/mL	
Fresh	/	27	77	
24h	RT (18-25°C)	25	71	
7 days	2-8°C	26	74	

<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
-------------------	---

**Date : 2017-11-06**

**QC Manager : S. LECOURT**





**BIOPHEN™ Edoxaban Control Low**

**REF** 225401

**LOT** F1701138  2020-03-24

**UNIT** F1701138

	<b>UNIT</b>	<b>TARGET VALUE</b>	<b>ACCEPTANCE RANGE</b>	<b>WHO STD</b>
<b>CI</b>	ng/mL	27	17 - 37	NA
<b>LOT</b> F171101138				
<b>CII</b>		77	62 - 92	
<b>LOT</b> F171101138				