

## ANALYSIS CERTIFICATE

**BIOPHEN EDOXABAN CALIBRATOR - #226501**

**Lot : F1701130**

**QC release : 2017-11-14**

**Expiration date : 2020-03-21**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
CAL1 : Calibrator 1	4 vials	30	F171101130	2020-03-21
CAL2 : Calibrator 2	4 vials	30	F171101130	2020-03-21
CAL3 : Calibrator 3	4 vials	30	F171101130	2020-03-21

*805*

# ANALYSIS CERTIFICATE

**BIOPHEN EDOXABAN CALIBRATOR - #226501**

**Lot : F1701130**

**Qc release : 2017-11-14**

**Expiration date : 2020-03-21**

Analytical data	Specifications																																						
<b>1. Within lot homogeneity (on N vials)</b> <div style="text-align: center; margin-top: 10px;"><u>mean OD</u></div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">N= 10</td> <td style="width: 35%;">CAL1: 1,926</td> <td style="width: 15%;">CV: 0,6 %</td> <td style="width: 35%; text-align: right;">CV (OD) ≤ 2%</td> </tr> <tr> <td>N= 10</td> <td>CAL2: 1,458</td> <td>CV: 0,6 %</td> <td style="text-align: right;">CV (OD) ≤ 2%</td> </tr> <tr> <td>N= 10</td> <td>CAL3: 1,122</td> <td>CV: 0,6 %</td> <td style="text-align: right;">CV (OD) ≤ 2%</td> </tr> </table>		N= 10	CAL1: 1,926	CV: 0,6 %	CV (OD) ≤ 2%	N= 10	CAL2: 1,458	CV: 0,6 %	CV (OD) ≤ 2%	N= 10	CAL3: 1,122	CV: 0,6 %	CV (OD) ≤ 2%																										
N= 10	CAL1: 1,926	CV: 0,6 %	CV (OD) ≤ 2%																																				
N= 10	CAL2: 1,458	CV: 0,6 %	CV (OD) ≤ 2%																																				
N= 10	CAL3: 1,122	CV: 0,6 %	CV (OD) ≤ 2%																																				
<b>2. Concentration [C] and Standard Deviation (SD)</b> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 15%;">N series</th> <th style="width: 25%;">[C] ng/mL</th> <th style="width: 45%;">SD</th> </tr> </thead> <tbody> <tr> <td>CAL1</td> <td style="text-align: center;">9</td> <td style="text-align: center;">0</td> <td style="text-align: center;">7,7</td> </tr> <tr> <td>CAL2</td> <td style="text-align: center;">9</td> <td style="text-align: center;">255</td> <td style="text-align: center;">7,6</td> </tr> <tr> <td>CAL3</td> <td style="text-align: center;">9</td> <td style="text-align: center;">496</td> <td style="text-align: center;">14,9</td> </tr> </tbody> </table> <div style="margin-top: 10px;">           CAL1: ≤ 40 ng/ml            CAL2: 200-300 ng/mL            CAL3: 400-600 ng/mL         </div>		Controls	N series	[C] ng/mL	SD	CAL1	9	0	7,7	CAL2	9	255	7,6	CAL3	9	496	14,9																						
Controls	N series	[C] ng/mL	SD																																				
CAL1	9	0	7,7																																				
CAL2	9	255	7,6																																				
CAL3	9	496	14,9																																				
<b>3. Aspect</b> <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 60%;">Slightly opalescent to clear</td> <td rowspan="3" style="width: 30%; vertical-align: top; padding-left: 10px;">           a) Slightly opalescent to clear            b) No coagulum            c) Stable solution         </td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>No coagulum</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Stable solution</td> </tr> </table>		<input checked="" type="checkbox"/>	Slightly opalescent to clear	a) Slightly opalescent to clear b) No coagulum c) Stable solution	<input checked="" type="checkbox"/>	No coagulum	<input checked="" type="checkbox"/>	Stable solution																															
<input checked="" type="checkbox"/>	Slightly opalescent to clear	a) Slightly opalescent to clear b) No coagulum c) Stable solution																																					
<input checked="" type="checkbox"/>	No coagulum																																						
<input checked="" type="checkbox"/>	Stable solution																																						
<b>4. Stability of reconstituted reagents</b> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th rowspan="2" style="width: 10%;"></th> <th rowspan="2" style="width: 10%;"></th> <th style="width: 15%;">Fresh</th> <th style="width: 15%;">24h</th> <th style="width: 15%;">7 days</th> </tr> <tr> <th style="text-align: center;">/</th> <th style="text-align: center;">RT(18-25°C)</th> <th style="text-align: center;">2-8°C</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="text-align: center; vertical-align: middle;">CAL1</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">24</td> <td style="text-align: center;">23</td> <td style="text-align: center;">23</td> </tr> <tr> <td style="text-align: center;">Δ C</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">1</td> <td style="text-align: center;">1</td> </tr> <tr> <td rowspan="2" style="text-align: center; vertical-align: middle;">CAL2</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">243</td> <td style="text-align: center;">224</td> <td style="text-align: center;">233</td> </tr> <tr> <td style="text-align: center;">Δ C</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">19</td> <td style="text-align: center;">10</td> </tr> <tr> <td rowspan="3" style="text-align: center; vertical-align: middle;">CAL3</td> <td rowspan="2" style="text-align: center; vertical-align: middle;">ng/mL</td> <td style="text-align: center;">499</td> <td style="text-align: center;">/</td> <td style="text-align: center;">482</td> </tr> <tr> <td style="text-align: center;">500 *</td> <td style="text-align: center;">479</td> <td style="text-align: center;">/</td> </tr> <tr> <td style="text-align: center;">Δ %</td> <td style="text-align: center;">NA</td> <td></td> <td></td> </tr> </tbody> </table> <div style="margin-top: 10px; text-align: right;">           24 hours at RT and 7 days at 2-8°C:             Δ [C] ≤ 30 ng/mL         </div>				Fresh	24h	7 days	/	RT(18-25°C)	2-8°C	CAL1	ng/mL	24	23	23	Δ C	NA	1	1	CAL2	ng/mL	243	224	233	Δ C	NA	19	10	CAL3	ng/mL	499	/	482	500 *	479	/	Δ %	NA		
				Fresh	24h	7 days																																	
		/	RT(18-25°C)	2-8°C																																			
CAL1	ng/mL	24	23	23																																			
	Δ C	NA	1	1																																			
CAL2	ng/mL	243	224	233																																			
	Δ C	NA	19	10																																			
CAL3	ng/mL	499	/	482																																			
		500 *	479	/																																			
	Δ %	NA																																					

\* Cal3 fresh only for Cal3 RT24H

SAS

## ANALYSIS CERTIFICATE

**BIOPHEN EDOXABAN CALIBRATOR - #226501**

**Lot : F1701130**

**QC release : 2017-11-14**

**Expiration date : 2020-03-21**

Analytical data	Specifications															
<p><b>5. <u>Calibration curve</u></b></p> <p style="text-align: center;">Instrument : CS5100</p> <p style="text-align: center;">Method : Biophen Hep                      Lot F1700493</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">ng/mL</th> <th style="text-align: center;">A<sub>405</sub></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL 1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0,812</td> </tr> <tr> <td style="text-align: center;">CAL 2</td> <td style="text-align: center;">255</td> <td style="text-align: center;">0,537</td> </tr> <tr> <td style="text-align: center;">CAL 3</td> <td style="text-align: center;">496</td> <td style="text-align: center;">0,328</td> </tr> </tbody> </table>	ng/mL		A <sub>405</sub>	CAL 1	0	0,812	CAL 2	255	0,537	CAL 3	496	0,328				
ng/mL		A <sub>405</sub>														
CAL 1	0	0,812														
CAL 2	255	0,537														
CAL 3	496	0,328														
<p><b>6. <u>Linearity of the calibration</u></b></p> <p style="text-align: center;">R<sup>2</sup>                      0,996</p>	<p>R<sup>2</sup> ≥ 0.98</p>															
<p><b>7. <u>Accuracy</u></b></p> <p style="text-align: center;">Instrument : CS5100</p> <p style="text-align: center;">Method : Biophen Hep</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">CONTROLS</th> <th style="text-align: center;">TV*</th> <th style="text-align: center;">MV*</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1701137</td> <td style="text-align: center;">148</td> <td style="text-align: center;">139</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1701137</td> <td style="text-align: center;">287</td> <td style="text-align: center;">276</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value                      *MV: Measured Value</p>	CONTROLS			TV*	MV*	C1	Lot	F1701137	148	139	C2	Lot	F1701137	287	276	<p style="text-align: center;">MV* within the acceptance range</p> <p style="text-align: center;">[111 - 185] ng/mL</p> <p style="text-align: center;">[244 - 330] ng/mL</p>
CONTROLS			TV*	MV*												
C1	Lot	F1701137	148	139												
C2	Lot	F1701137	287	276												
<p><b><u>Comments :</u></b></p>	<p><input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b></p>															

**Date : 2017-11-14**

**QC Manager : S. LECOURT**





**HYPHEN  
BioMed**

ZAC Neuville Université - 155 rue d'Eragry  
95000 Neuville sur Oise (France)  
Tel: +33.1.34.40.65.10 - Fax: +33.1.34.48.72.36  
Web site: [www.hyphen-biomed.com](http://www.hyphen-biomed.com)



**BIOPHEN™ Edoxaban Calibrator**

**REF** 226501

**LOT** F1701130  **2020-03-21**

	<b>UNIT</b>	<b>TARGET VALUE</b>	<b>WHO STD</b>
<b>CAL 1</b> <b>LOT</b> F171101130	ng/mL	0	NA
<b>CAL 2</b> <b>LOT</b> F171101130		255	
<b>CAL 3</b> <b>LOT</b> F171101130		496	