

ANALYSIS CERTIFICATE

BIOPHEN EDOXABAN CALIBRATOR LOW - #226401

Lot : F1701136

QC release : 2017-11-14

Expiration date : 2020-03-21

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL I : Calibrator I	4 vials	30	F171101136	2020-03-21
CAL II : Calibrator II	4 vials	30	F171101136	2020-03-21
CAL III : Calibrator III	4 vials	30	F171101136	2020-03-21

SPS

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Analytical data				Specifications																																			
1. <u>Within lot homogeneity (on N vials)</u>																																							
mean OD																																							
N= 10	CAL I: 1,518	CV: 0,6 %	CV (OD) ≤ 2%																																				
N= 10	CAL II: 1,266	CV: 0,5 %	CV (OD) ≤ 2%																																				
N= 10	CAL III: 1,028	CV: 0,7 %	CV (OD) ≤ 2%																																				
2. <u>Concentration [C] and Standard Deviation (SD)</u>																																							
<table border="1" style="width: 100%; border-collapse: collapse;"> <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: 15%;">SD</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL I</td> <td style="text-align: center;">9</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,8</td> </tr> <tr> <td style="text-align: center;">CAL II</td> <td style="text-align: center;">9</td> <td style="text-align: center;">51</td> <td style="text-align: center;">1,9</td> </tr> <tr> <td style="text-align: center;">CAL III</td> <td style="text-align: center;">9</td> <td style="text-align: center;">107</td> <td style="text-align: center;">3,7</td> </tr> </tbody> </table>					Controls	N series	[C] ng/mL	SD	CAL I	9	0	1,8	CAL II	9	51	1,9	CAL III	9	107	3,7																			
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CAL I	9	0	1,8																																				
CAL II	9	51	1,9																																				
CAL III	9	107	3,7																																				
				CAL I: < 15 ng/ml CAL II: 40-60 ng/mL CAL III: 80-120 ng/mL																																			
3. <u>Aspect</u>																																							
<input checked="" type="checkbox"/>	Slightly opalescent to clear			a) Slightly opalescent to clear																																			
<input checked="" type="checkbox"/>	No coagulum			b) No coagulum																																			
<input checked="" type="checkbox"/>	Stable solution			c) Stable solution																																			
4. <u>Stability of reconstituted reagents</u>																																							
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" rowspan="2"></th> <th style="width: 10%;">Fresh</th> <th style="width: 15%;">24h</th> <th style="width: 15%;">7 days</th> </tr> <tr> <th style="text-align: center;">I</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;">CAL I</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">4,0</td> <td style="text-align: center;">4,0</td> <td style="text-align: center;">3,6</td> </tr> <tr> <td style="text-align: center;">Δ C</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0,4</td> </tr> <tr> <td rowspan="2" style="text-align: center;">CAL II</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">50</td> <td style="text-align: center;">46</td> <td style="text-align: center;">48</td> </tr> <tr> <td style="text-align: center;">Δ C</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">4</td> <td style="text-align: center;">2</td> </tr> <tr> <td rowspan="2" style="text-align: center;">CAL III</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">108</td> <td style="text-align: center;">100</td> <td style="text-align: center;">104</td> </tr> <tr> <td style="text-align: center;">Δ C</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">8</td> <td style="text-align: center;">4</td> </tr> </tbody> </table>							Fresh	24h	7 days	I	RT(18-25°C)	2-8°C	CAL I	ng/mL	4,0	4,0	3,6	Δ C	NA	0	0,4	CAL II	ng/mL	50	46	48	Δ C	NA	4	2	CAL III	ng/mL	108	100	104	Δ C	NA	8	4
		Fresh	24h	7 days																																			
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				24 hours at RT(18-25°C) and 7 days at 2-8°C: Δ [C] ≤ 15 ng/mL																																			

SD

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Analytical data	Specifications															
<p>5. <u>Calibration curve</u></p> <p style="text-align: center;">Instrument : CS5100</p> <p>Method : Biophen DiXal Lot F1700574</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;">A₄₀₅</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL I</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,491</td> </tr> <tr> <td style="text-align: center;">CAL II</td> <td style="text-align: center;">51</td> <td style="text-align: center;">1,228</td> </tr> <tr> <td style="text-align: center;">CAL III</td> <td style="text-align: center;">107</td> <td style="text-align: center;">0,995</td> </tr> </tbody> </table>	ng/mL		A ₄₀₅	CAL I	0	1,491	CAL II	51	1,228	CAL III	107	0,995				
ng/mL		A ₄₀₅														
CAL I	0	1,491														
CAL II	51	1,228														
CAL III	107	0,995														
<p>6. <u>Linearity of the calibration</u></p> <p style="text-align: center;">R² 1,00</p>	<p>R² ≥ 0.98</p>															
<p>7. <u>Accuracy</u></p> <p style="text-align: center;">Instrument : CS5100</p> <p style="text-align: center;">Method : Biophen DiXal</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;">C I</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1701138</td> <td style="text-align: center;">27</td> <td style="text-align: center;">24</td> </tr> <tr> <td style="text-align: center;">C II</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1701138</td> <td style="text-align: center;">77</td> <td style="text-align: center;">74</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p>	CONTROLS			TV*	MV*	C I	Lot	F1701138	27	24	C II	Lot	F1701138	77	74	<p style="text-align: center;">MV* within the acceptance range</p> <p style="text-align: center;">[17 - 37] ng/mL [62 - 92] ng/mL</p>
CONTROLS			TV*	MV*												
C I	Lot	F1701138	27	24												
C II	Lot	F1701138	77	74												
<p><u>Comments :</u></p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>															

Date : 2017-11-14

QC Manager :

S. LECOURT



BIOPHEN™ Edoxaban Calibrator Low

REF 226401

LOT F1701136  **2020-03-21**

UNIT	TARGET VALUE	WHO STD
<p>CAL I</p> <p>LOT F171101136</p>	0	NA
<p>CAL II</p> <p>LOT F171101136</p>	51	
<p>CAL III</p> <p>LOT F171101136</p>	107	