

ANALYSIS CERTIFICATE

BIOPHEN™ Apixaban Calibrator Low - #226101

Lot :

**F1700235
F1700241**

QC release: 2017-04-06

Expiration date :

2019-08-17

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171100235 F171300241	2019-08-17
CAL2 : Calibrator 2	4 vials	30	F171100235 F171300241	2019-08-17
CAL3 : Calibrator 3	4 vials	30	F171100235 F171300241	2019-08-17

SOS

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F1700235

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Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
N= 10 CV: 1,1 %	CV (OD) ≤ 2%
N= 10 CV: 0,6 %	CV (OD) ≤ 2%
N= 10 CV: 1,5 %	CV (OD) ≤ 2%

2. <u>Concentration [C] and Standard Deviation (SD)</u>													
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Controls</th> <th style="width: 40%;">[C] ng/mL</th> <th style="width: 40%;">SD</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0,23</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">50</td> <td style="text-align: center;">4,3</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">101</td> <td style="text-align: center;">8,7</td> </tr> </tbody> </table>	Controls	[C] ng/mL	SD	CAL1	0	0,23	CAL2	50	4,3	CAL3	101	8,7	CAL1: < 20 ng/ml CAL2: 40-60 ng/mL CAL3: 80-120 ng/mL
Controls	[C] ng/mL	SD											
CAL1	0	0,23											
CAL2	50	4,3											
CAL3	101	8,7											

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

4. <u>Stability of reconstituted reagents</u>					
		Fresh	48h	7 days	
		/	RT	2-8°C	
CAL1	ng/mL	0	0	0	48 hours at RT: $\Delta [C] \leq 15 \text{ ng/ml}$ 7 days at 2-8°C: $\Delta [C] \leq 15 \text{ ng/ml}$
	$\Delta [C]$	NA	0	0	
CAL2	ng/mL	49	49	50	
	$\Delta [C]$	NA	0	1	
CAL3	ng/mL	101	101	100	
	$\Delta [C]$	NA	0	1	

ms

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<p>5. <u>Calibration curve</u></p> <p style="text-align: center;"><input type="checkbox"/> Manual method <input checked="" type="checkbox"/> STAR</p> <p style="text-align: center;">BIOPHEN DiXal Lot F1601136</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 20%;">ng/ml</th> <th style="width: 20%;"></th> <th style="width: 20%;">A₄₀₅</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">0</td> <td></td> <td style="text-align: center;">2,444</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">50</td> <td></td> <td style="text-align: center;">1,766</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">101</td> <td></td> <td style="text-align: center;">1,173</td> </tr> </tbody> </table>		ng/ml		A ₄₀₅	Cal 1	0		2,444	Cal 2	50		1,766	Cal 3	101		1,173	
	ng/ml		A ₄₀₅														
Cal 1	0		2,444														
Cal 2	50		1,766														
Cal 3	101		1,173														

<p>6. <u>Linearity</u></p> <p style="text-align: center;">R² 0,998</p>	<p>R² ≥ 0.98</p>
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<p>7. <u>Accuracy</u></p> <p style="text-align: center;"><input type="checkbox"/> Manual method <input checked="" type="checkbox"/> STAR</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;">44801-1</td> <td style="text-align: center;">25</td> <td style="text-align: center;">26</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">44801-2</td> <td style="text-align: center;">77</td> <td style="text-align: center;">79</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p>	CONTROLS			TV*	MV*	C1	Lot	44801-1	25	26	C2	Lot	44801-2	77	79	<p>MV* within the acceptance range</p> <p style="text-align: center;">[15 - 35] [62 - 92]</p>
CONTROLS			TV*	MV*												
C1	Lot	44801-1	25	26												
C2	Lot	44801-2	77	79												

<p>Comments :</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
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Date : 2017-04-06

QC Manager : S.LECOURT

BIOPHEN™ Apixaban Calibrator Low

REF 226101

LOT F1700241  2019-08-17

UNIT	TARGET VALUE	WHO STD
<p>CAL I</p> <p>LOT F171300241</p>	0	N/A
<p>CAL II</p> <p>LOT F171300241</p>	50	
<p>CAL III</p> <p>LOT F171300241</p>	101	