

ANALYSIS CERTIFICATE

BIOPHEN™ Apixaban Calibrator Low - #226101

**Lot : F1701092
F1701093**

QC release: 2017-11-03

Expiration date : 2020-03-14

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171401092 F171201093	2020-03-14
CAL2 : Calibrator 2	4 vials	30	F171401092 F171201093	2020-03-14
CAL3 : Calibrator 3	4 vials	30	F171401092 F171201093	2020-03-14

SR

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BIOPHEN™ Apixaban Calibrator Low - #226101

F1701092

Lot : F1701093

QC release: 2017-11-03

Expiration date : 2020-03-14

Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
N= 15 CV: 0,9 %	CV (OD) ≤ 2%
N= 15 CV: 1,1 %	CV (OD) ≤ 2%
N= 15 CV: 1,3 %	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: 30%;">[C] ng/mL</th> <th style="width: 20%;">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;">1,484</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">48</td> <td style="text-align: center;">2,051</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">109</td> <td style="text-align: center;">5,622</td> </tr> </tbody> </table>	Controls	[C] ng/mL	SD	CAL1	0	1,484	CAL2	48	2,051	CAL3	109	5,622	CAL1: < 20 ng/ml CAL2: 40-60 ng/mL CAL3: 80-120 ng/mL
Controls	[C] ng/mL	SD											
CAL1	0	1,484											
CAL2	48	2,051											
CAL3	109	5,622											

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	53	51	52	
	$\Delta [C]$	NA	2	1	
CAL3	ng/mL	110	109	102	
	$\Delta [C]$	NA	1	8	

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Analytical data	Specifications												
<p>5. Calibration curve</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 F1700574</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%; text-align: center;">ng/ml</th> <th style="width: 20%; text-align: center;">A₄₀₅</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;">2,337</td> </tr> <tr> <td style="text-align: center;">Cal 2</td> <td style="text-align: center;">48</td> <td style="text-align: center;">1,651</td> </tr> <tr> <td style="text-align: center;">Cal 3</td> <td style="text-align: center;">109</td> <td style="text-align: center;">0,937</td> </tr> </tbody> </table>		ng/ml	A ₄₀₅	Cal 1	0	2,337	Cal 2	48	1,651	Cal 3	109	0,937	
	ng/ml	A ₄₀₅											
Cal 1	0	2,337											
Cal 2	48	1,651											
Cal 3	109	0,937											

<p>6. Linearity</p> <p style="text-align: center;">R² 0,996</p>	<p>R² ≥ 0.98</p>
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<p>7. Accuracy</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;">F1700491</td> <td style="text-align: center;">24</td> <td style="text-align: center;">28</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1700491</td> <td style="text-align: center;">75</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*	C1	Lot	F1700491	24	28	C2	Lot	F1700491	75	74	<p>MV* within the acceptance range</p> <p style="text-align: center;">[14 - 34] [60 - 90]</p>
CONTROLS			TV*	MV*												
C1	Lot	F1700491	24	28												
C2	Lot	F1700491	75	74												

<p>Comments :</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
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Date : 2017-11-03

QC Manager : S. LECOURT



**HYPHEN
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BIOPHEN™ Apixaban Calibrator Low

REF 226101

LOT F1701092  **2020-03-14**

	UNIT	TARGET VALUE	WHO STD
CAL I LOT F171401092	ng/mL	0	NA
CAL II LOT F171401092		48	
CAL III LOT F171401092		109	