

## ANALYSIS CERTIFICATE

**BIOPHEN™ Apixaban Calibrator - #226201**

**Lot :** F1700659  
F1700660

**QC release:** 2017-08-30

**Expiration date :** 2019-12-27

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171200659 F171100660	2019-12-27
CAL2 : Calibrator 2	4 vials	30	F171200659 F171100660	2019-12-27
CAL3 : Calibrator 3	4 vials	30	F171200659 F171100660	2019-12-27

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Analytical data	Specifications
<b>1. <u>Within lot reproducibility</u></b>	
N= 15                      CV:            0,9 %	CV (OD) ≤ 2%
N= 15                      CV:            0,8 %	CV (OD) ≤ 2%
N= 15                      CV:            1,3 %	CV (OD) ≤ 2%

<b>2. <u>Concentration [C] and Standard Deviation (SD)</u></b>													
<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;">7,4</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">290</td> <td style="text-align: center;">18,5</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">578</td> <td style="text-align: center;">28,1</td> </tr> </tbody> </table>	Controls	[C] ng/mL	SD	CAL1	0	7,4	CAL2	290	18,5	CAL3	578	28,1	CAL1: < 50 ng/ml CAL2: 200-400 ng/mL CAL3: 500-700 ng/mL
Controls	[C] ng/mL	SD											
CAL1	0	7,4											
CAL2	290	18,5											
CAL3	578	28,1											

<b>3. <u>Aspect</u></b>	
<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

<b>4. <u>Stability of reconstituted reagents</u></b>					
		Fresh	48h	7 days	
		/	RT	2-8°C	
CAL1	ng/mL	12	11	12	<b>48 hours at RT:</b> $\Delta [C] \leq 30 \text{ ng/ml}$  <b>7 days at 2-8°C:</b> $\Delta [C] \leq 30 \text{ ng/ml}$
	$\Delta [C]$	NA	1	0	
CAL2	ng/mL	280	278	265	
	$\Delta [C]$	NA	2	15	
CAL3	ng/mL	591	587	598	
	$\Delta [C]$	NA	4	7	

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Analytical data	Specifications												
<p><b>5. Calibration curve</b></p> <p style="text-align: center;"><input type="checkbox"/> Manual method      <input checked="" type="checkbox"/> STAR</p> <p style="text-align: center;"><b>BIOPHEN DiXal                      Lot F1700574</b></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;">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;">2,529</td> </tr> <tr> <td style="text-align: center;">Cal 2</td> <td style="text-align: center;">290</td> <td style="text-align: center;">1,799</td> </tr> <tr> <td style="text-align: center;">Cal 3</td> <td style="text-align: center;">578</td> <td style="text-align: center;">1,116</td> </tr> </tbody> </table>		ng/ml	A <sub>405</sub>	Cal 1	0	2,529	Cal 2	290	1,799	Cal 3	578	1,116	
	ng/ml	A <sub>405</sub>											
Cal 1	0	2,529											
Cal 2	290	1,799											
Cal 3	578	1,116											

<p><b>6. Linearity</b></p> <p style="text-align: center;"><b>R<sup>2</sup>                      0,998</b></p>	<p><b>R<sup>2</sup> ≥ 0.98</b></p>
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<p><b>7. Accuracy</b></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;">F1700656</td> <td style="text-align: center;">178</td> <td style="text-align: center;">191</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1700656</td> <td style="text-align: center;">384</td> <td style="text-align: center;">405</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value      *MV: Measured Value</p>	CONTROLS			TV*	MV*	C1	Lot	F1700656	178	191	C2	Lot	F1700656	384	405	<p>MV* within the acceptance range</p> <p style="text-align: center;">[ 151 - 205 ]          [ 326 - 442 ]</p>
CONTROLS			TV*	MV*												
C1	Lot	F1700656	178	191												
C2	Lot	F1700656	384	405												

<p>Comments :</p>	<p><input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b></p>
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**Date : 2017-08-30**

**QC Manager : S. LECOURT**





**HYPHEN  
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**REF** 226201

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**EXP** 2019-12-27

	<b>UNIT</b>	<b>TARGET VALUE</b>	<b>WHO STD</b>
<b>CAL 1</b>	ng/mL	0	NA
<b>LOT F171200659</b>			
<b>CAL 2</b>			
<b>LOT F171200659</b>		290	
<b>CAL 3</b>		578	
<b>LOT F171200659</b>			