

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

305

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Lot : F1700660

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

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	12	11	12	48 hours at RT: $\Delta [C] \leq 30$ ng/ml 7 days at 2-8°C: $\Delta [C] \leq 30$ 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>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;">2,529</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 ₄₀₅	Cal 1	0	2,529	Cal 2	290	1,799	Cal 3	578	1,116	
	ng/ml	A ₄₀₅											
Cal 1	0	2,529											
Cal 2	290	1,799											
Cal 3	578	1,116											

<p>6. Linearity</p> <p style="text-align: center;">R² 0,998</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;">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"/> PASSED IN COMPLIANCE</p>
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Date : 2017-08-30

QC Manager : S. LECOURT



BIOPHEN™ Apixaban Calibrator

REF 226201

LOT F1700659  2019-12-27

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