

ANALYSIS CERTIFICATE

BIOPHEN™ Rivaroxaban Plasma Calibrator - #222701

Lot : F1700285 / F1700286

QC release: 2017-04-20

Expiration date :

2019-09-03

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171100285 / F171100286	2019-09-03
CAL2 : Calibrator 2	4 vials	30	F171100285 / F171100286	2019-09-03
CAL3 : Calibrator 3	4 vials	30	F171100285 / F171100286	2019-09-03

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Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
N= 25 CV: 0,6 %	CV (OD) ≤ 2%
N= 25 CV: 0,5 %	CV (OD) ≤ 2%
N= 25 CV: 0,7 %	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;">3,7</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">250</td> <td style="text-align: center;">11,2</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">494</td> <td style="text-align: center;">20,6</td> </tr> </tbody> </table>	Controls	[C] ng/mL	SD	CAL1	0	3,7	CAL2	250	11,2	CAL3	494	20,6	CAL1: ≤ 50 ng/ml CAL2: 200-300 ng/mL CAL3: 400-600 ng/mL
Controls	[C] ng/mL	SD											
CAL1	0	3,7											
CAL2	250	11,2											
CAL3	494	20,6											

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: Δ [C] ≤ 30 ng/ml 7 days at 2-8°C: Δ [C] ≤ 30 ng/ml
	Δ [C]	NA	1	0	
CAL2	ng/mL	232	236	233	
	Δ [C]	NA	4	1	
CAL3	ng/mL	472	475	485	
	Δ [C]	NA	3	13	

SPS

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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 F1600443 </p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 15%;">ng/ml</th> <th style="width: 15%;">A₄₀₅</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">2,678</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">250</td> <td style="text-align: center;">1,799</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">494</td> <td style="text-align: center;">0,995</td> </tr> </tbody> </table>		ng/ml	A ₄₀₅	Cal 1	0	2,678	Cal 2	250	1,799	Cal 3	494	0,995	
	ng/ml	A ₄₀₅											
Cal 1	0	2,678											
Cal 2	250	1,799											
Cal 3	494	0,995											

<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">CONTROLS</th> <th>TV*</th> <th>MV*</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>Lot</td> <td>F1600888</td> <td style="text-align: center;">104</td> <td style="text-align: center;">118</td> </tr> <tr> <td>C2</td> <td>Lot</td> <td>F1600888</td> <td style="text-align: center;">316</td> <td style="text-align: center;">325</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p>	CONTROLS			TV*	MV*	C1	Lot	F1600888	104	118	C2	Lot	F1600888	316	325	<p>MV* within the acceptance range</p> <p style="text-align: center;"> [73 - 135] [265 - 367] </p>
CONTROLS			TV*	MV*												
C1	Lot	F1600888	104	118												
C2	Lot	F1600888	316	325												

Comments :

**PASSED
IN COMPLIANCE**

Date : 2017-04-20

QC Manager : S. LECOURT



BIOPHEN™ Rivaroxaban Plasma Calibrator

REF 222701

LOT F1700285

2019-09-03

UNIT	TARGET VALUE	WHO STD
CAL 1 LOT F171100285	0	
CAL 2 LOT F171100285	250	NA
CAL 3 LOT F171100285	494	NA