

ANALYSIS CERTIFICATE

BIOPHEN™ Rivaroxaban Control Low - #225101

**Lot : F1700629
F1700630**

QC release : 2017-06-30

Expiration date : 2019-11-24

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F171200629 F171100630	2019-11-24
C2 : Control 2	6 vials	30	F171200629 F171100630	2019-11-24

SRS

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Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
N= 15 C1(OD): 1,072 CV: 0,3 %	OD : CV ≤ 2%
N= 15 C2(OD): 0,770 CV: 1,1 %	OD : CV ≤ 2%

2. <u>Concentration and acceptance range</u>	Target value:									
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Controls</th> <th style="width: 25%;">[C] ng/mL</th> <th style="width: 50%;">Acceptance range (ng/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">31</td> <td style="text-align: center;">21-41</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">86</td> <td style="text-align: center;">69-103</td> </tr> </tbody> </table>	Controls	[C] ng/mL	Acceptance range (ng/mL)	C1	31	21-41	C2	86	69-103	C1: 15 to 35 ng/mL C2: 45 to 105 ng/mL
Controls	[C] ng/mL	Acceptance range (ng/mL)								
C1	31	21-41								
C2	86	69-103								

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

4. <u>Stability of reconstituted reagents</u>																			
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th>C1</th> <th>C2</th> </tr> <tr> <th>ng/mL</th> <th>ng/mL</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">31</td> <td style="text-align: center;">84</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">18-25°C</td> <td style="text-align: center;">31</td> <td style="text-align: center;">85</td> </tr> <tr> <td style="text-align: center;">7 days</td> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">32</td> <td style="text-align: center;">86</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	31	84	48h	18-25°C	31	85	7 days	2-8°C	32	86	48h at 18-25°C Controls within the acceptance range 7 days at 2-8°C Controls within the acceptance range
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	31	84																
48h	18-25°C	31	85																
7 days	2-8°C	32	86																

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-06-30

QC Manager : S. LECOURT



BIOPHEN™ Rivaroxaban Control Low

REF 225101

LOT F1700629

 2019-11-24

	UNIT	TARGET VALUE	ACCEPTANCE RANGE	WHO STD
<p>CI</p> <p>LOT F171200629</p>	ng/mL	31	21 – 41	NA
<p>CII</p> <p>LOT F171200629</p>		86	69 – 103	