

ANALYSIS CERTIFICATE

BIOPHEN™ Rivaroxaban Control Plasma - #224501

**Lot : F1700865
F1700866**

QC release : 2017-09-01

Expiration date : 2020-01-18

Components	Volume	Exp. (months)	Lot #	Exp Date
C1 : Control 1	6 vials	30	F171200865 F171100866	2020-01-18
C2 : Control 2	6 vials	30	F171200865 F171100866	2020-01-18

Elc.

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F1700865
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Analytical data	Specifications
1. <u>Within lot reproducibility</u> N= 40 C1(OD): 1,725 CV: 0,4 % N= 40 C2(OD): 1,328 CV: 0,6 %	OD : CV ≤ 2% OD : CV ≤ 2%

2. <u>Concentration and acceptance range</u> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Controls</th> <th style="width: 20%;">[C] ng/mL</th> <th style="width: 60%;">Acceptance range (ng/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">94</td> <td style="text-align: center;">66 - 122</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">309</td> <td style="text-align: center;">260 - 358</td> </tr> </tbody> </table>	Controls	[C] ng/mL	Acceptance range (ng/mL)	C1	94	66 - 122	C2	309	260 - 358	Target value: C1: 50 to 150 ng/mL C2: 250 to 350 ng/mL
Controls	[C] ng/mL	Acceptance range (ng/mL)								
C1	94	66 - 122								
C2	309	260 - 358								

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
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4. <u>Stability of reconstituted reagents</u> <table border="1" style="margin-left: auto; margin-right: 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;">87</td> <td style="text-align: center;">317</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">18-25°C</td> <td style="text-align: center;">89</td> <td style="text-align: center;">307</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;">86</td> <td style="text-align: center;">308</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	87	317	48h	18-25°C	89	307	7 days	2-8°C	86	308	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	/	87	317																
48h	18-25°C	89	307																
7 days	2-8°C	86	308																

Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-09-01

QC Manager : S. LECOURT

S. Lecourt



BIOPHEN™ Rivaroxaban Control Plasma

REF 224501

LOT F1700865

 2020-01-18

	UNIT	TARGET VALUE	ACCEPTANCE RANGE	WHO STD
C1	ng/mL	94	[66 – 122]	NA
LOT F171200865				
C2	ng/mL	309	[260 – 358]	NA
LOT F171200865				