

ANALYSIS CERTIFICATE

BIOPHEN™ Apixaban Control - #225301

**Lot : F1700656
F1700657**

QC release : 2017-07-11

Expiration date : 2019-11-30

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F171400656 F171100657	2019-11-30
C2 : Control 2	6 vials	30	F171400656 F171100657	2019-11-30

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F1700656
Lot : F1700657

QC release : 2017-07-11

Expiration date : 2019-11-30

Analytical data	Specifications
1. <u>Within lot reproducibility</u> N= 20 CV: 0,5 % N= 20 CV: 0,8 %	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;">178</td> <td style="text-align: center;">151-205</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">384</td> <td style="text-align: center;">326-442</td> </tr> </tbody> </table>	Controls	[C] ng/mL	Acceptance range (ng/mL)	C1	178	151-205	C2	384	326-442	Target value: C1: 140 to 260 ng/mL C2: 340 to 460 ng/mL
Controls	[C] ng/mL	Acceptance range (ng/mL)								
C1	178	151-205								
C2	384	326-442								

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 style="width: 20%;">C1</th> <th style="width: 20%;">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;">176</td> <td style="text-align: center;">382</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">18-25°C</td> <td style="text-align: center;">176</td> <td style="text-align: center;">383</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;">175</td> <td style="text-align: center;">389</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	176	382	48h	18-25°C	176	383	7 days	2-8°C	175	389	<u>48h at 18-25°C</u> Controls within the acceptance range <u>7 days at 2-8°C</u> Controls within the acceptance range
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	176	382																
48h	18-25°C	176	383																
7 days	2-8°C	175	389																

<u>Comments :</u> 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-07-11

QC Manager : S. LECOURT


 F820-11/BI/5301-v5



BIOPHEN™ Apixaban Control

REF 225301

LOT F1700656

EXP 2019-11-30

	UNIT	TARGET VALUE	ACCEPTANCE RANGE	WHO STD
C1	ng/mL	178	151-205	NA
LOT F17140656				
C2		384	326-442	
LOT F171400656				