

## ANALYSIS CERTIFICATE

**BIOPHEN™ Apixaban Control Low - #225201**

**Lot : F1700491  
F1700492**

**QC release : 2017-06-06**

**Expiration date : 2019-10-29**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
C1 : Control 1	6 vials	30	F171300491 F171100492	2019-10-29
C2 : Control 2	6 vials	30	F171300491 F171100492	2019-10-29

*SMS*

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Analytical data	Specifications
<b>1. <u>Within lot reproducibility</u></b>  <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;">N= 20</div> <div style="width: 45%;">CV: 0,9 %</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;">N= 20</div> <div style="width: 45%;">CV: 0,9 %</div> </div>	OD : CV ≤ 2%  OD : CV ≤ 2%

<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <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;">24</td> <td style="text-align: center;">[ 14 - 34 ]</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">75</td> <td style="text-align: center;">[ 60 - 90 ]</td> </tr> </tbody> </table>	Controls	[C] ng/mL	Acceptance range (ng/mL)	C1	24	[ 14 - 34 ]	C2	75	[ 60 - 90 ]	<b>Target value:</b>  C1: 15 to 35 ng/mL  C2: 45 to 105 ng/mL
Controls	[C] ng/mL	Acceptance range (ng/mL)								
C1	24	[ 14 - 34 ]								
C2	75	[ 60 - 90 ]								

<b>3. <u>Aspect</u></b>  <div style="display: flex; justify-content: space-between;"> <div style="width: 45%; text-align: center;"> <input checked="" type="checkbox"/> Slightly opalescent to clear   <input checked="" type="checkbox"/> No coagulum   <input checked="" type="checkbox"/> Stable solution         </div> <div style="width: 45%; vertical-align: top;">           a) Slightly opalescent to clear            b) No coagulum             c) Stable solution         </div> </div>	
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<b>4. <u>Stability of reconstituted reagents</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th style="width: 15%;">C1</th> <th style="width: 15%;">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;">27</td> <td style="text-align: center;">80</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">18-25°C</td> <td style="text-align: center;">26</td> <td style="text-align: center;">78</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;">27</td> <td style="text-align: center;">81</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	27	80	48h	18-25°C	26	78	7 days	2-8°C	27	81	<b>48h at 18-25°C</b> Controls within the acceptance range  <b>7 days at 2-8°C</b> Controls within the acceptance range
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	27	80																
48h	18-25°C	26	78																
7 days	2-8°C	27	81																

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

**QC Manager :** S. LECOURT






**BIOPHEN™ Apixaban Control Low**

**REF** 225201

**LOT** F1700491

 2019-10-29

	<b>UNIT</b>	<b>TARGET VALUE</b>	<b>ACCEPTANCE RANGE</b>	<b>WHO STD</b>
<b>CI</b>	ng/mL	24	[ 14 – 34 ]	NA
<b>LOT</b> F171300491				
<b>CII</b>		75	[ 60 – 90 ]	
<b>LOT</b> F171300491				