

ANALYSIS CERTIFICATE

BIOPHEN™ Apixaban Control Low - #225201

**Lot : F1700491
F1700492**

QC release : 2017-06-06

Expiration date : 2019-10-29

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

SMS

ANALYSIS CERTIFICATE

BIOPHEN™ Apixaban Control Low - #225201

F1700491
Lot : F1700492

QC release : 2017-06-06

Expiration date : 2019-10-29

| Analytical data | Specifications |
|--|----------------------------------|
| 1. <u>Within lot reproducibility</u> <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% |

| 2. <u>Concentration and acceptance range</u> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <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] | Target value: 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] | | | | | | | | |

| | |
|---|--|
| 3. <u>Aspect</u> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <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> | |
|---|--|

| 4. <u>Stability of reconstituted reagents</u> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <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 | 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 | / | 27 | 80 | | | | | | | | | | | | | | | | |
| 48h | 18-25°C | 26 | 78 | | | | | | | | | | | | | | | | |
| 7 days | 2-8°C | 27 | 81 | | | | | | | | | | | | | | | | |

| | |
|---------------------------|---|
| Comments : | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE |
|---------------------------|---|

Date : 2017-06-06

QC Manager : S. LECOURT





BIOPHEN™ Apixaban Control Low

REF 225201

LOT F1700491



2019-10-29

| | UNIT | TARGET VALUE | ACCEPTANCE RANGE | WHO STD |
|-----------------------|-------------|---------------------|-------------------------|----------------|
| CI | ng/mL | 24 | [14 – 34] | NA |
| LOT F171300491 | | | | |
| CI | | 75 | [60 – 90] | |
| LOT F171300491 | | | | |