

# ANALYSIS CERTIFICATE

**BIOPHEN™ Apixaban Control - #225301**

**Lot : F1601254**

**QC release : 2017-01-18**

**Expiration date : 2019-05-25**

| <b>Components</b> | <b>Volume</b> | <b>Exp.<br/>(months)</b> | <b>Lot #</b> | <b>Exp.<br/>date</b> |
|-------------------|---------------|--------------------------|--------------|----------------------|
| C1 : Control 1    | 6 vials       | 30                       | F161301254   | 2019-05-25           |
| C2 : Control 2    | 6 vials       | 30                       | F161301254   | 2019-05-25           |

*SAS*

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| Analytical data   | Specifications                   |
|---|----------------------------------|
| <b>1. <u>Within lot reproducibility</u></b><br><br>N= 25                      CV:    0,3 %<br><br>N= 25                      CV:    0,8 % | OD : CV ≤ 2%<br><br>OD : CV ≤ 2% |

| <b>2. <u>Concentration and acceptance range</u></b><br><br><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;">180</td> <td style="text-align: center;">153-207</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">370</td> <td style="text-align: center;">314-426</td> </tr> </tbody> </table> | Controls  | [C] ng/mL                | Acceptance range (ng/mL) | C1 | 180 | 153-207 | C2 | 370 | 314-426 | <b>Target value:</b><br><br>C1: 140 to 260 ng/mL<br><br>C2: 340 to 460 ng/mL |
|--|-----------|--------------------------|--------------------------|----|-----|---------|----|-----|---------|--|
| Controls   | [C] ng/mL | Acceptance range (ng/mL) |                          |    |     |         |    |     |         |  |
| C1   | 180       | 153-207                  |                          |    |     |         |    |     |         |  |
| C2   | 370       | 314-426                  |                          |    |     |         |    |     |         |  |

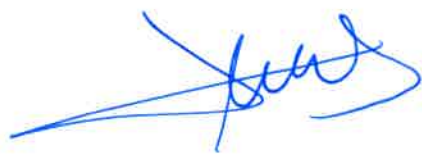
|   |   |
|---|---|
| <b>3. <u>Aspect</u></b><br><br><input checked="" type="checkbox"/> Slightly opalescent to clear<br><br><input checked="" type="checkbox"/> No coagulum<br><br><input checked="" type="checkbox"/> Stable solution | a) Slightly opalescent to clear<br>b) No coagulum<br><br>c) Stable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

| <b>4. <u>Stability of reconstituted reagents</u></b><br><br><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;">178</td> <td style="text-align: center;">367</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">18-25°C</td> <td style="text-align: center;">174</td> <td style="text-align: center;">371</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;">177</td> <td style="text-align: center;">364</td> </tr> </tbody> </table> |         | Temp. | C1    | C2 | ng/mL | ng/mL | Fresh | / | 178 | 367 | 48h | 18-25°C | 174 | 371 | 7 days | 2-8°C | 177 | 364 | <b>48h at 18-25°C</b><br>Controls within the acceptance range<br><br><b>7 days at 2-8°C</b><br>Controls within the acceptance range |
|--|---------|-------|-------|----|-------|-------|-------|---|-----|-----|-----|---------|-----|-----|--------|-------|-----|-----|---|
|  |         |       | Temp. | C1 | C2    |       |       |   |     |     |     |         |     |     |        |       |     |     |   |
|  | ng/mL   | ng/mL |       |    |       |       |       |   |     |     |     |         |     |     |        |       |     |     |   |
| Fresh  | /       | 178   | 367   |    |       |       |       |   |     |     |     |         |     |     |        |       |     |     |   |
| 48h  | 18-25°C | 174   | 371   |    |       |       |       |   |     |     |     |         |     |     |        |       |     |     |   |
| 7 days   | 2-8°C   | 177   | 364   |    |       |       |       |   |     |     |     |         |     |     |        |       |     |     |   |

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

**Date : 2017-01-18**

**QC Manager : S.LECOURT**



BIOPHEN™ Apixaban Control

REF 225301

LOT F1601254

 2019-05-25

|                | UNIT  | TARGET VALUE | ACCEPTANCE RANGE | WHO STD |
|----------------|-------|--------------|------------------|---------|
| C1             |       | 180          | 153-207          |         |
| LOT F161301254 |       |              |                  |         |
| C2             | ng/mL |              |                  |         |
| LOT F161301254 |       | 370          | 314-426          | NA      |