

ANALYSIS CERTIFICATE

BIOPHEN™ Rivaroxaban Calibrator Low - #226001

Lot : F1700627

QC release: 2017-07-03

Expiration date : 2019-11-24

| Components | Volume | Exp. (months) | Lot # | Exp. date |
|------------------------|---------------|--------------------------|--------------|----------------------|
| CAL I : Calibrator 1 | 4 vials | 30 | F171200627 | 2019-11-24 |
| CAL II : Calibrator 2 | 4 vials | 30 | F171200627 | 2019-11-24 |
| CAL III : Calibrator 3 | 4 vials | 30 | F171200627 | 2019-11-24 |

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QC release: 2017-07-03

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| Analytical data | | Specifications | | | | | | | | | | | | | |
|---|-----------|--|-----------|-------|-------|--------|------|--------|-------|-----|---------|-----|-----|---|--|
| 1. <u>Within lot reproducibility</u> | | | | | | | | | | | | | | | |
| N= 10 | CV: 0,3 % | CV (OD) ≤ 2% | | | | | | | | | | | | | |
| N= 10 | CV: 0,9 % | CV (OD) ≤ 2% | | | | | | | | | | | | | |
| N= 10 | CV: 1,0 % | CV (OD) ≤ 2% | | | | | | | | | | | | | |
| 2. <u>Concentration [C] and Standard Deviation (SD)</u> | | | | | | | | | | | | | | | |
| <table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Controls</th> <th style="text-align: center;">[C] ng/mL</th> <th style="text-align: center;">SD</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL I</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,41</td> </tr> <tr> <td style="text-align: center;">CAL II</td> <td style="text-align: center;">60</td> <td style="text-align: center;">3,2</td> </tr> <tr> <td style="text-align: center;">CAL III</td> <td style="text-align: center;">105</td> <td style="text-align: center;">4,5</td> </tr> </tbody> </table> | | Controls | [C] ng/mL | SD | CAL I | 0 | 1,41 | CAL II | 60 | 3,2 | CAL III | 105 | 4,5 | CAL1: < 20 ng/ml CAL2: 40-60 ng/mL CAL3: 80-120 ng/mL | |
| Controls | [C] ng/mL | SD | | | | | | | | | | | | | |
| CAL I | 0 | 1,41 | | | | | | | | | | | | | |
| CAL II | 60 | 3,2 | | | | | | | | | | | | | |
| CAL III | 105 | 4,5 | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | |
| 4. <u>Stability of reconstituted reagents</u> | | | | | | | | | | | | | | | |
| | | <table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Fresh</th> <th style="text-align: center;">48h</th> <th style="text-align: center;">7 days</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">/</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">2-8°C</td> </tr> </tbody> </table> | | Fresh | 48h | 7 days | / | RT | 2-8°C | | | | | | |
| Fresh | 48h | 7 days | | | | | | | | | | | | | |
| / | RT | 2-8°C | | | | | | | | | | | | | |
| CAL I | ng/mL | 2 | 1 | 1 | | | | | | | | | | | |
| | Δ [C] | NA | 1 | 1 | | | | | | | | | | | |
| CAL II | ng/mL | 61 | 59 | 60 | | | | | | | | | | | |
| | Δ [C] | NA | 2 | 1 | | | | | | | | | | | |
| CAL III | ng/mL | 104 | 105 | 105 | | | | | | | | | | | |
| | Δ [C] | NA | 1 | 1 | | | | | | | | | | | |
| | | 48 hours at RT: Δ [C] ≤ 15 ng/ml 7 days at 2-8°C: Δ [C] ≤ 15 ng/ml | | | | | | | | | | | | | |



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|--|----------------|------------------|------------------|-------|---|-------|--------|----|-------|---------|-----|-------|--|
| <p>5. Calibration curve</p> <p style="text-align: center;"><input type="checkbox"/> Manual method <input checked="" type="checkbox"/> STAR</p> <p style="text-align: center;">BIOPHEN DiXal Lot F1600443</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">ng/ml</th> <th style="text-align: center;">A₄₀₅</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL I</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,988</td> </tr> <tr> <td style="text-align: center;">CAL II</td> <td style="text-align: center;">60</td> <td style="text-align: center;">1,104</td> </tr> <tr> <td style="text-align: center;">CAL III</td> <td style="text-align: center;">105</td> <td style="text-align: center;">0,713</td> </tr> </tbody> </table> | ng/ml | | A ₄₀₅ | CAL I | 0 | 1,988 | CAL II | 60 | 1,104 | CAL III | 105 | 0,713 | |
| ng/ml | | A ₄₀₅ | | | | | | | | | | | |
| CAL I | 0 | 1,988 | | | | | | | | | | | |
| CAL II | 60 | 1,104 | | | | | | | | | | | |
| CAL III | 105 | 0,713 | | | | | | | | | | | |

| | |
|---|-----------------------------|
| <p>6. Linearity</p> <p style="text-align: center;">R² 1,00</p> | <p>R² ≥ 0.98</p> |
|---|-----------------------------|

| <p>7. Accuracy</p> <p style="text-align: center;"><input type="checkbox"/> Manual method <input checked="" type="checkbox"/> STAR</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">CONTROLS</th> <th style="text-align: center;">TV*</th> <th style="text-align: center;">MV*</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C I</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1601248</td> <td style="text-align: center;">24</td> <td style="text-align: center;">23</td> </tr> <tr> <td style="text-align: center;">C II</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1601248</td> <td style="text-align: center;">84</td> <td style="text-align: center;">86</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p> | CONTROLS | | | TV* | MV* | C I | Lot | F1601248 | 24 | 23 | C II | Lot | F1601248 | 84 | 86 | <p>MV* within the acceptance range</p> <p style="text-align: center;">[14 - 34] [67 - 101]</p> |
|---|----------|----------|-----|-----|-----|-----|-----|----------|----|----|------|-----|----------|----|----|--|
| CONTROLS | | | TV* | MV* | | | | | | | | | | | | |
| C I | Lot | F1601248 | 24 | 23 | | | | | | | | | | | | |
| C II | Lot | F1601248 | 84 | 86 | | | | | | | | | | | | |

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

Date : 2017-07-03

QC Manager : S. LECOURT





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BIOPHEN™ Rivaroxaban Calibrator Low

REF 226001

LOT F1700627  2019-11-24

| | UNIT | TARGET VALUE | WHO STD |
|---------------------------|-------|--------------|---------|
| CAL I LOT F171200627 | ng/mL | 0 | NA |
| CAL II LOT F171200627 | | 60 | |
| CAL III LOT F171200627 | | 105 | |