

HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ BIVALIRUDIN CONTROL
Product Code : 225701
Lot No. : F1801436 / F1801435
Expiration date : 2021-04-13

| Components | Quantity | Lot | Expiration Date |
|------------|----------|--------------------------|-----------------|
| C1 | 3 vials | F181101436 F181101435 | 2021-04-13 |
| C2 | 3 vials | F181101436 F181101435 | 2021-04-13 |

| Analytical Data | Specification | Result |
|-----------------|---|--------------------------|
| Concentration | C1 : 1.25 -1.75 µg/ml C2 : 3.3 - 4.3 µg/ml | 1.37 µg/mL 3.62 µg/mL |

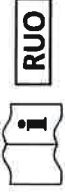
This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval : 2019-05-10

Quality Control Manager :

C.DUNOIS





BIOPHEN™ Bivalirudin Control

REF 225701-RUO

LOT F1801435

2021-04-13

| | UNIT | TARGET VALUE | ACCEPTANCE RANGE | WHO STD |
|------------------------------------|-------------|---------------------|-------------------------|----------------|
| C1 LOT F181101435 | µg/mL | 1.37 | [1.12 – 1.62] | NA |
| C2 LOT F181101435 | | 3.62 | [2.90 – 4.34] | |