

ANALYSIS CERTIFICATE

BIOPHEN® APIXABAN CONTROL - #225301

Lot : 52703

QC release : 13/08/2015

Expiration date : 2018-01

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	6 vials	30	150703A	52703-1	2018-01
C2 : Control 2	6 vials	30	150703B	52703-2	2018-01

SAS

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Analytical data	Specifications
1. <u>Within lot reproducibility (N ≥ 10)</u> N= 20 CV: 0,6 % N= 20 CV: 0,8 %	OD : CV ≤ 2% OD : CV ≤ 2%

2. <u>Concentration and acceptance range</u>	Target value: C1: 140 to 260 ng/mL C2: 340 to 460 ng/mL									
<table border="1" style="margin: 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;">185</td> <td style="text-align: center;">157-213</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">381</td> <td style="text-align: center;">324-438</td> </tr> </tbody> </table>	Controls	[C] ng/mL	Acceptance range (ng/mL)	C1	185	157-213	C2	381	324-438	
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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
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4. <u>Stability of reconstituted reagents</u>	<u>48h at RT</u> Controls within the acceptance range <u>7 days at 2-8°C</u> Controls within the acceptance range																		
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Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 13/08/2015

QC Manager : S. LECOURT



BIOPHEN® APIXABAN CONTROL
225301

Pour diagnostic *in vitro* exclusivement

FRANCAIS

Lot : 52703 - Exp. : 2018-01

C1 (Contrôle 1) Lot : 52703-1
[C]: 185 ng/mL
Intervalle de confiance: 157-213 ng/mL

C2 (Contrôle 2) Lot : 52703-2
[C]: 381 ng/mL
Intervalle de confiance: 324 - 438 ng/mL

Approved
17/03/15
[Signature]

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