

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN Anti Ila (2 stages) - #221025

Lot : F1500030

QC Release : 15/01/2016

Expiration date : 2018-05-29

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : Human Antithrombin	2 vials	30	F151100030	F151100030	2018-06-01
R2 : Human Thrombin	2 vials	30	F151100030	F151100030	2018-06-04
R3 : Thrombin substrate	2 vials	30	F151100030	F151100030	2018-05-29
R4 : Reaction buffer	4 vials	30	F151100030	F151100030	2018-06-02

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ANALYSIS CERTIFICATE

BIOPHEN HEPARIN Anti IIa (2 stages) - #221025

Lot : F1500030

QC Release : 15/01/2016

Expiration date : 2018-05-29

Analytical data	Specifications
<p>1. <u>AT</u></p> <p>a. Reproducibility (A405 for 0 IU/ml heparin) N= 25 Mean (A405) : 1,382 CV : 1,1 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay on raw material) 1,5 IU</p> <p>c. Indicative AT content per vial (A280nm/Lowry on raw material) 150 µg</p> <p>d. SDS PAGE (on raw material) 1 major band of about 58 000 Da</p> <p>e. Absence of heparin Absence</p>	<p style="text-align: center;">N≥5</p> <p style="text-align: center;">≤ 5 %</p> <p style="text-align: center;">≥ 1.2 IU</p> <p style="text-align: center;">1 major band of about 58,000 Da</p> <p style="text-align: center;">Absence</p>
<p>2. <u>Thrombin substrate</u></p> <p>a. Blank value N= 10 Mean (A405) : 0,118</p> <p>b. Reproducibility (A405 for 0 IU/ml heparin) N= 25 Mean (A405) : 1,576 CV : 2,8 %</p> <p>c. Indicative content per vial (raw material) 6,25 mg (about 11,3 µmol)</p> <p>d. HPLC analysis purity grade (raw material) 99 %</p> <p>e. Experimental molecular weight (raw material) 552 Da</p>	<p style="text-align: center;">N≥5 A405 ≤ 0.30</p> <p style="text-align: center;">N≥5 ≤ 5 %</p> <p style="text-align: center;">≥ 95%</p> <p style="text-align: center;">553 ± 5 Da</p>
<p>3. <u>Thrombin</u></p> <p>a. Reproducibility (A405 for 0 IU/ml heparin) N= 25 Mean (A405) : 1,720 CV : 2,8 %</p> <p>b. SDS PAGE (5% acrylamide) (on raw material) 1 major band of about 35 000 Da</p> <p>c. Indicative IIa content per vial (Lowry on raw material) 36,7 µg</p> <p>d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa) 80 NIH (or IU)</p> <p>e. Indicative specific chromogenic activity (on raw material) (chromogenic assay using CS-01(38)) 6,78 nkats/µg</p>	<p style="text-align: center;">N≥5 ≤ 5 %</p> <p style="text-align: center;">1 major band of about 35,000 Da</p>
<p>4. <u>Reaction buffer (N ≥ 3)</u></p> <p style="margin-left: 100px;">Volume : >25 ml pH 8,48</p> <p>Aspect : <input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p>	<p style="text-align: center;">≥ 25 ml [8.20 - 8.60]</p> <p style="text-align: center;">Clear - Transparent</p>

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Analytical data	Specifications																					
<p>5. Assay reactivity</p> <p>a. <u>Manual method (concentration in the tested dilution)</u></p> <table border="1" style="margin-left: 40px;"> <thead> <tr> <th>UFH UI/ml</th> <th>0.0</th> <th>0.01</th> <th>0.02</th> <th>0.03</th> <th>0.04</th> <th>r²</th> </tr> </thead> <tbody> <tr> <td>A405 UFH plasma</td> <td>1,744</td> <td>1,482</td> <td>1,123</td> <td>0,914</td> <td>0,752</td> <td>0,994</td> </tr> <tr> <td>A405 UFH purified</td> <td>1,929</td> <td>1,574</td> <td>1,325</td> <td>1,075</td> <td>0,909</td> <td>0,996</td> </tr> </tbody> </table>	UFH UI/ml	0.0	0.01	0.02	0.03	0.04	r ²	A405 UFH plasma	1,744	1,482	1,123	0,914	0,752	0,994	A405 UFH purified	1,929	1,574	1,325	1,075	0,909	0,996	<p>$\Delta A405 (0-0.04) \geq 0.70$</p> <p>$r^2 \geq 0.98$</p>
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<p>6. HNF Detection threshold (concentration in the tested dilution)</p> <p>In Plasma 0,002 IU/ml</p> <p>In Purified solution 0,0007 IU/ml</p>	<p>≤ 0.002 IU/ml</p>
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<p>7. Stability of reconstituted reagents</p> <p>Reagents tested after 15 days at 2-8°C, or 4 days at RT (18-25°C) or Frozen/thawed</p> <p>A405 values</p> <table border="1" style="margin-left: 40px;"> <thead> <tr> <th>UFH IU/ml</th> <th>0.0</th> <th>0.01</th> <th>0.02</th> <th>0.03</th> <th>0.04</th> <th>r²</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Freshly restored</td> <td>1,641</td> <td>1,282</td> <td>0,982</td> <td>0,768</td> <td>0,622</td> <td>0,997</td> </tr> <tr> <td>1,704</td> <td>1,491</td> <td>1,249</td> <td>1,025</td> <td>0,865</td> <td>0,988</td> </tr> <tr> <td>15 days at 2-8°C</td> <td>1,571</td> <td>1,222</td> <td>0,942</td> <td>0,696</td> <td>0,521</td> <td>0,998</td> </tr> <tr> <td>4 days at RT</td> <td>1,834</td> <td>1,519</td> <td>1,272</td> <td>1,038</td> <td>0,863</td> <td>0,996</td> </tr> <tr> <td>Frozen & Thawed</td> <td>1,588</td> <td>1,311</td> <td>1,036</td> <td>0,831</td> <td>0,664</td> <td>0,999</td> </tr> </tbody> </table>	UFH IU/ml	0.0	0.01	0.02	0.03	0.04	r ²	Freshly restored	1,641	1,282	0,982	0,768	0,622	0,997	1,704	1,491	1,249	1,025	0,865	0,988	15 days at 2-8°C	1,571	1,222	0,942	0,696	0,521	0,998	4 days at RT	1,834	1,519	1,272	1,038	0,863	0,996	Frozen & Thawed	1,588	1,311	1,036	0,831	0,664	0,999	<p>(1)</p> <p>(2)</p> <p>$r^2 \geq 0.98$</p> <p>$\Delta A405 (0 \text{ to } 0.04 \text{ IU/ml}) \geq 0.70$</p> <p>$\Delta A405 (0 \text{ UI/mL})$ between series $\leq 10\%$</p>
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<p>Comments :</p> <p>(1) fresh for "15 days at 2-8° C"</p> <p>(2) fresh for "4 days at RT" and "frozen and thawed"</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
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