

ANALYSIS CERTIFICATE

Ristocetin - #AG004K

F1700400
F1700402
Lot : F1700403

QC Release : 2017-04-27

Expiration date : 2019-09-30

Components	Qty	Exp. (months)	Lot #	Exp. date
Ristocetin	3 vials	30	F1700400 F1700402 F1700403	2019-09-30

305

ANALYSIS CERTIFICATE

Ristocetin - #AG004K

Lot :

**F1700400
 F1700402
 F1700403**

QC Release : 2017-04-27

Expiration date :

2019-09-30

Analytical data	Specifications															
<p>a. Intra-lot homogeneity (Ristocetin 1.5mg/ml):</p> <p>Sample : PRP <input type="checkbox"/> Lyophilized platelets <input checked="" type="checkbox"/></p> <p style="margin-left: 100px;">N = 15 vials</p> <p style="margin-left: 100px;">CV (%AgregMax) = 6,3 %</p> <p>Aspect: in compliance / not in compliance</p>	<p>CV ≤ 10%</p> <p>Transparent, slightly white/brown</p>															
<p>b. Reactivity :</p> <p style="margin-left: 40px;">N = 3 normal PRP</p> <table border="1" style="margin-left: 40px; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>[ristocetin] (mg/ml)</th> <th>% AgregMax (Mean)</th> </tr> </thead> <tbody> <tr> <td>1.5</td> <td>98</td> </tr> <tr> <td>1</td> <td>93</td> </tr> <tr> <td>0.5</td> <td>4</td> </tr> </tbody> </table>	[ristocetin] (mg/ml)	% AgregMax (Mean)	1.5	98	1	93	0.5	4	<p>%AgregMax (1,5mg/mL) ≥ 80%</p> <p>%AgregMax (1,0mg/mL) ≥ 70%</p> <p>%AgregMax (0,5mg/mL) < 10%</p>							
[ristocetin] (mg/ml)	% AgregMax (Mean)															
1.5	98															
1	93															
0.5	4															
<p>c. Stability of reconstituted reagent (tested at 1mg/ml)</p> <p>Sample : PRP <input checked="" type="checkbox"/> Lyophilized platelets <input type="checkbox"/></p> <table border="1" style="margin-left: 40px; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Storage time and temperature:</th> <th>%AgregMax</th> <th>Δ%</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>97</td> <td>na</td> </tr> <tr> <td>24 hours at RT (18-25°C)</td> <td>92</td> <td>5</td> </tr> <tr> <td>7 days at 2-8°C</td> <td>106</td> <td>9</td> </tr> <tr> <td>Frozen (-20°C)/thawed (RT)</td> <td>94</td> <td>3</td> </tr> </tbody> </table>	Storage time and temperature:	%AgregMax	Δ%	Fresh	97	na	24 hours at RT (18-25°C)	92	5	7 days at 2-8°C	106	9	Frozen (-20°C)/thawed (RT)	94	3	<p>Δ% (%AgregMax stored/fresh)</p> <p>≤20%</p>
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<p>Comments :</p>	<p><input checked="" type="checkbox"/> Passed in Compliance</p>
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Date : 2017-04-17

QC Manager :

S.LECOURT


 F820-11/AG/004K-v5