

 <b>La Châtre</b>	<b>RELEASE CERTIFICATE</b> <b>LA CHÂTRE PLANT</b>	Formulaire N° : C01-TEST-F Révision N° : G Document de référence : SOP N° : TEST-F
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<b>CODE</b>	<b>RGB8110B</b>	<b>BATCH</b>	<b>FC20J07L41</b>
Single InterSol (500ml) container for processing and storage of Platelets with male luer lock connector			

**Manufacturing Date**      October 7, 2020  
**Expiry Date**              2022-03-31

### CONFORMITY OF TESTS

\* N/A means Not Applicable

<b>BACTERIAL ENDOTOXIN TEST</b>			
<b>Turbidimetric Kinetic Method (TEST-B-03)</b>			
Results Primary pack :	PASS	Date passed :	October 21, 2020
Results Secondary pack :	N/A*	Date passed :	N/A*
			<b>PASS</b> <input checked="" type="checkbox"/>


<b>STERILITY TEST</b> <input checked="" type="checkbox"/> <b>or</b> <b>PARAMETRIC RELEASE</b> <input type="checkbox"/>			
<b>Sterility Test (TEST-B-13)</b>		<b>Parametric Release</b>	
Number of positives / number of units tested :	0/20	Date passed :	October 27, 2020
Result of sterility test :	PASS	Result of parametric release :	N/A*
			<b>PASS</b> <input checked="" type="checkbox"/>

<b>BACTERIOLOGY – BIOBURDEN (TEST-B-17)</b>	<b>PASS</b> <input checked="" type="checkbox"/>
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<b>FINAL PHYSICAL TESTING (TEST-C)</b>	<b>PASS</b> <input checked="" type="checkbox"/>
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<b>FINAL CHEMICAL ANALYSIS</b>			
Performed on batch :	FC20J07L41	Code number :	RGB8110B
Valid for batches :	N/A*	Code number :	N/A*
			<b>PASS</b> <input checked="" type="checkbox"/>

<b>OTHER INFORMATION</b>			
Batch ASAHI Filter (if applicable) :	N/A*	Manufactured by :	N/A*

<b>QUANTITY RELEASED</b>	<b>5040</b>	<b>UNITS</b>
QA manager or delegate  <b>M. Rovina , October 28, 2020</b>		

Note for CE-marked codes : This is to certify that this product was manufactured according to current European Union GMP guidelines and fulfills the requirements of the MDD 93/42EC and additional local regulations.

Note for other codes : This is to certify that this product was manufactured according to current GMP guidelines and fulfills the requirements of the local regulations.

Containers : Containers released in compliance with ISO3826 and E.P. Testing certificate available upon request.

# Certificate of analysis for solutions

**Batch** : FC20J07L41  
**Solution** : 231516002  
**SOLUTION PASIII N:EU**

Test	Product Limit	Result
SODIUM ACETATE Trihydrate	Identification : positive 4.20 - 4.64 g/l	Conform 4.35 g/l
SODIUM CITRATE Dihydrate	Identification : positive 3.02 - 3.34 g/l	Conform 3.15 g/l
PHOSPHATE Identification ( test A)	POSITIVE	Conform
CHLORIDE Identification	POSITIVE	Conform
pH	7.0 - 7.5 UpH	7.3 UpH
PHOSPHATE	2.55 - 2.81 g/l	2.62 g/l
SODIUM	Identification : positive 182 - 202 mEq/l	Conform 187 mEq/l
CHLORIDE as NaCl	4.29 - 4.75 g/l	4.47 g/l
PARTICULATE MATTER	10µm : 25 per mL 25µm : 3 per mL	Conform

Solution released ☒ YES ☐ NO

**A. DURANDEAU**



October 19, 2020