



La Châtre

RELEASE CERTIFICATE
LA CHÂTRE PLANT

Formulaire N° : C01-TEST-F
Révision N° : G
Document de référence :
SOP N° : TEST-F

CODE

RGB8110B

BATCH

FC20J07L41

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

BACTERIAL ENDOTOXIN TEST

Turbidimetric Kinetic Method (TEST-B-03)

Results Primary pack : PASS Date passed : October 21, 2020

Results Secondary pack : N/A* Date passed : N/A*

PASS

STERILITY TEST or PARAMETRIC RELEASE

Sterility Test (TEST-B-13)

Parametric Release

Number of positives / 0/20 Date October
number of units passed : 27, 2020
tested :

Result of N/A*
parametric
release :

Result of sterility test : PASS

PASS

BACTERIOLOGY – BIOBURDEN (TEST-B-17)

PASS

FINAL PHYSICAL TESTING (TEST-C)

PASS

FINAL CHEMICAL ANALYSIS

Performed on batch : FC20J07L41 Code number : RGB8110B

Valid for batches : N/A* Code number : N/A*

PASS

OTHER INFORMATION

Batch ASAHI Filter (if applicable) : N/A* Manufactured by : N/A*

QUANTITY RELEASED

5040

UNITS

QA manager or delegate

M. Rovina , October 28, 2020

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

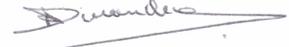
SOLUTION PASIII N:EU

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