

CODE	INT2504B	LOT	CE20J26L71
		Expiry Date	2022-09

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE20K16L11	Amotosalen
	2	N/A	1
	3	N/A	2
PCT sub-assembly	1	CE20J26L71	3
			CAD material

DESCRIPTION : INTERCEPT Platelet Processing Set with Dual Storage Containers

CONFORMITY OF TESTS RESULTS

Product	PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)		
	Limits (≤)	Date Passed	Results
Final product	0.125 EU / mL	November 24, 2020	PASS
Amotosalen solution sub-assembly	<input checked="" type="checkbox"/> 3 mM → 2.0 EU / mL OR <input type="checkbox"/> 6 mM → 0.8 EU / mL	1	November 24, 2020
		2	N/A
		3	N/A
PCT sub-assembly	0.25 EU / mL	1	October 28, 2020

Disposition : **PASS**

BACTERIOLOGY-BIOBURDEN (TEST-B-17 / TEST-B-09)	Disposition : PASS <input checked="" type="checkbox"/>
FINAL PHYSICAL TESTING (TEST-C)	Disposition : PASS <input checked="" type="checkbox"/>
pH ANALYSIS ON CONNECTED KIT (TEST-A)	Disposition : PASS <input checked="" type="checkbox"/>
AMOTOSALEN FINAL CHEMICAL ANALYSIS (TEST-A-01)	Disposition : PASS <input checked="" type="checkbox"/>

STERILITY		
Amotosalen solution	Steam sterilization cycle according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
PCT sub-assembly	Gamma irradiation according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
Connected product	E-Beam irradiation according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
Sterility Test (TEST-B-13)	No positives	CONFORM <input checked="" type="checkbox"/>

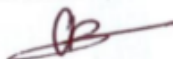
Disposition : **PASS**

Note : N/A means Not Applicable PCT means Photo Chemical Treatment

QUANTITY


6768 UNITS

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature
C. BERTHOMIER



December 14, 2020

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature



Romain LELIEVRE
Dec 15th, 2020

This is to certify that this product was manufactured according to current Good Manufacturing Practice and fulfills the requirements of the Device Master Record.