



**CERTIFICATE OF CONFORMITY
INTERCEPT PRODUCT**



Formulaire N° : C22-TEST-F
Révision N° : B
SOP N° : TEST-F
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CODE	INT2504B	LOT	CE23C13A01
		Expiry Date	2025-05

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE23F07L11	Amotosalen
	2	N/A	1
	3	N/A	2
PCT sub-assembly	1	CE23C13A01	CAD material
			3
			20625B / 20626B / 20721A / 20722A / 20711B / 20711A / 20710B / 20723B / 20725B

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	June 21, 2023	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	June 26, 2023
		2	N/A
		3	N/A
PCT sub-assembly	0.25 EU / mL	1	June 21, 2023

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 10344 UNITS

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature

P. MANDRELIER

July 25th, 2023

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature

DocuSigned by:

Daniela da Costa Pinto



Signer Name: Daniela da Costa Pinto
Signing Reason: I approve this document
Signing Time: 7/27/2023 | 2:19:51 AM PDT

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