

CODE	INT3104B	LOT	CE19G12L72
		Expiry Date	2021-06

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE19H01L11	Amotosalen
	2	N/A	1
	3	N/A	2
PCT sub-assembly	1	CE19G12L72	CAD material
			3

DESCRIPTION : INTERCEPT Processing Set for Plasma

CONFORMITY OF TESTS RESULTS

Product	PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)		
	Limits (≤)	Date Passed	Results
Final product	0.125 EU / mL	August 7, 2019	PASS
Amotosalen solution sub-assembly	<input type="checkbox"/> 3 mM → 2.0 EU / mL OR <input checked="" type="checkbox"/> 6 mM → 0.8 EU / mL	1	August 8, 2019
		2	N/A
		3	N/A
PCT sub-assembly	0.25 EU / mL	1	July 17, 2019

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 **2592 UNITS**

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature

C. BERTHOMIER


September 11, 2019

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature


Romain LELIEVRE
Sept 11th 2019

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