ECP Reçu le
24 JAN. 2017
N°

4897542

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http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 24-Jan-2017 FR01S11793637-1-1

This is to certify that Synergy Health Marseille has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 Quality System - Medical Devices

ECP ENTEGRIS CLEANING PROCESS
Le Millénaire
395 rue Louis Lépine
34000 MONTPELLIER
FRANCE

DIVERSEY
Di ClearPlus IPA Airless VH1 7%
Batch : ENT 31245 17 006
M. L. AUGUSTE le 28/04/2017

Order Information

Account Number:	101999
Synergy Health Sales Part Reference:	1023388
Customer Reference Number:	CF170047 - 12/01/2017
Product Description:	ESSAI - ECP ENTEGRIS CLEANING PROCESS
Quantity Received:	1
Customer Unit Lot/Batch Number:	ENT31245 17 006(1c)
Other Process Details:	Customer required doses: 25.0 - 40.0 kGy

Irradiation Data

Date and Time of Irradiation:	24-JAN-2017 02:14
Calculated Minimum Dose kGy:	28.6
Calculated Maximum Dose kGy:	34.6

Irradiation Release Authorised By Synergy Health plc

ENTEGRIS CLEANING PROCESS
ECP
An Entegris Company

CONTROL REPORT

Diversey

Customer DIVERSEY	Management Quality Manual n° MMQ0000 (contractual)

Product : Clearklens IPA Airless VH1 70%		**Control report n°** :	CERT 17216
Specification reference :	NA		
Analyst :	JAR	**Purchase order n° :**	4701989407
		Date of receipt :	04/13/2017

PHYSICAL AND CHEMICAL PROPERTIES CONTROL

Customer's batch n° :	ENT31245 17 044	**ISOTRON certificate(s) n°** :	S117936370101
Date of manufacturing :	04/2017	**Produced quantity** :	170 x 0,25L
Expiry date :	02/2019	**FIDT N°** :	1896 ind 0
ECP's batch n° :	31245	**Date of analysis** :	04/13/2017

Résultats :

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Specific gravity (base) (21°C)	IDT0301	0,873	0,865 - 0,875
Appearance (base) 21°C	NA	Clear, colourless liquid	Clear, colourless liquid
Microbiological contagion of the EDI	IDT0236	6 CFU / 100 mL	< 10 CFU /100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion : [X] CONFORM [ ] NOT CONFORM

Batch released by M.L. AUGUSTE le 28/04/2017 C Auguste

Date : 04/26/2017	Written by : J. ARNOULD	Checked by : L. RUBINI

IMP 0180 - L

p° C Auguste

p° C Auguste

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Charles River
Endotoxin and Microbial Detection
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Email : Endosafe.labEU@crl.com

ANALYSIS REPORT
N° 130-171 - Page 1 / 3

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for customer n°: 220553

ENTEGRIS CLEANING PROCESS / ECP
A l'attention de Lorinda RUBINI
395 Rue Louis LEPINE
34000 MONTPELLIER

BACTERIAL ENDOTOXINS TEST
including test for interfering factors using 1 batch

Technical Contract

Technical questionnaire

Method

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

21 April 2017

Testing date

24 April 2017

Number of samples

1

Product
CLEARKLENS IPA 70% Airless

Endotoxin limit (Entegris)
0,25 IU/mL

1. Maximum Valid Dilution Calculation

Before the routine test, it is necessary to characterize the product in order to look for interference factors. Thanks to this step we can check if the sample is without inhibition or enhancement for the dilution of the routine test using 1 to 3 different lots of the product.

For drug products which have a published limit, the last dilution can't exceed the Maximum Valid Dilution or MVD :

$$MVD = \frac{\text{Endotoxin limit x Product potency}}{\text{Sensitivity}}$$

With :

Endotoxin limit : 0,25 IU/mL
Product potency : NA
λ = Sensitivity : 0,005 IU/mL

$$MVD = \frac{0{,}25\ IU/mL}{0{,}005\ IU/mL} = 50$$

cofrac ESSAIS
ACCREDITATION N° 1-5805
Scope available on www.cofrac.fr

Operator
Sara HULLY
Lab. Technician

25 AVR. 2017

Quality Reviewer

Not applicable to cGMP

Technical Reviewer

Vanessa SAVOYE
Adjointe technique laboratoire

25 AVR. 2017

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Technical Contract

Technical questionnaire

Method

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

21 April 2017

Testing date

24 April 2017

Number of samples

1

Product
CLEARKLENS IPA 70% Airless

Endotoxin limit (Entegris)
0,25 IU/mL

2. Test for Interfering Factors

Before the routine test, it is necessary to characterize the product in order to look for interference factors. Thanks to this step we can check if the sample is without inhibition or enhancement for the dilution of the routine test using 1 to 3 different lots of the product.

ID Produit

CLEARKLENS IPA 70 % Airless 250mL pouch with spray dosing pump

Operational Conditions

Sample is collected using the spray dosing pump and then diluted in LRW (LAL Reagent Water).

Dilution	pH *	Spike recovery**	Interference
1/1	7,1	NA	NA
1/2	7,1	NA	NA
1/5	7,2	NA	NA
1/50	7,2	80%	No interference

* : pH must be within 6 and 8
** : spike recovery must be within 50% and 200 %

Sample doesn't show any interference from dilution 1/50.

Note : *Results are valid only for (the) object(s) tested.*
Moreover, result(s) does not take into account the test uncertainty.

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Sensitivity

0,005 IU/mL

Sample delivery date

21 April 2017

Testing date

24 April 2017

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1

Product
CLEARKLENS IPA 70% Airless

Endotoxin limit (Entegris)
0,25 IU/mL

3. Endotoxin concentration of the test solution

The assay was performed in compliance with the European Pharmacopoeia in force, chapter "2.6.14 – Bacterial endotoxins", harmonized in collaboration with the American and Japanese Pharmacopoeias.

Product ID
CLEARKLENS IPA 70 % Airless 250mL pouch with spray dosing pump

Operational conditions
Unless otherwise specified, sample is tested at dilution 1/50 in LRW (LAL Reagent Water).

Batch / Sample / Number	Endotoxin amount	Units
ENT31245 17 006	**< 0,25**	**IU/mL**

Note : *Results are valid only for (the) object(s) tested.*
Moreover, result(s) does not take into account the test uncertainty.

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