

4897542

<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 CleanPens IPA Airless VHA 70%
Batch: ENT31245 17 006
M. L. AUGUSTE le 28/01/2017

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

Processing Site: M.I.N. 712 - Arnavaux, , Marseille Cedex 14, 13323 Phone No: +33 (0) 4 91 214 214

Registered Office: M.I.N. 712 - Arnavaux, 13323 Marseille Cedex 14, FRANCE

N° TVA: FR59 343 092 540

Page 1 of 1

CONTROL REPORT

Customer DIVERSEY		Management Quality Manual n° MMQ0000 (contractual)	
Product : Clearklens IPA Airless VH1 70%		Control report n° : CERT 17216	
Specification reference : NA		Purchase order n° : 4701989407	
Analyst : JAR		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 :



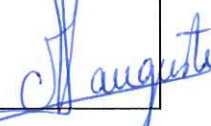
CONFORM



NOT CONFORM

Batch released by M. AUGUSTE

le 28/04/2017

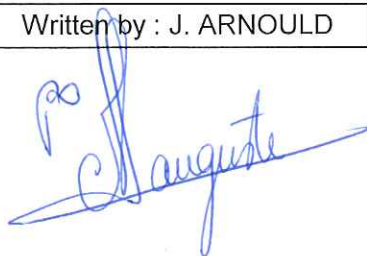


Date : 04/26/2017

Written by : J. ARNOULD

Checked by : L. RUBINI

IMP 0180 - L






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Endotoxin and Microbial Detection
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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

CLEARLENs 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 :

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

With :

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

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



Operator
Sara HULLY
Lab. Technician

Quality Reviewer

Not applicable to cGMP

Technical Reviewer

Vanessa SAVOYE
Adjointe technique laboratoire

25 AVR. 2017

microbial solutions

9 allée Moulin Berger - 69130 Ecully - France

Tel : 00 33 437 50 25 30 • Fax : 00 33 437 50 25 34 • www.criver.com

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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

CLEARLENs 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

CLEARLENs 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.



Operator
Sara HULLY
Lab. Technician

Quality Reviewer

Not applicable to cGMP

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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

CLEARLENs 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

CLEARLENs 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

ENT31245 17 006

Endotoxin amount Units

< 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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Lab. Technician

Quality Reviewer

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