CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED : **Synergy Health S.A.S.**

MIN 712 - Les ARNAVAUX
13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le
15 AVR. 2013
N° 130415 06A

CERTIFY THAT WE TREATED BY GAMMA RADIATION ACCORDING TO THE SPECIFIC CUSTOMER'S REQUIREMENTS AND TO :

- the specification of treatment # ESSAI 1 DOSE
- The requirements of the European Pharmacopeia

THE FOLLOWING PRODUCTS : (according to the customer's indication)

Customer	:	**ECP ENTEGRIS CLEANING PROCESS**
Product	:	IPA WIPE
Customer's reference	:	ORDER # CF130242 OF 12/03/2013
Quantity	:	1 PALLET
Irradiation date	:	2013.04.14
Irradiation dose	:	26.3 kGy to 43.0 kGy
Irradiation batch number	:	19038301

DIVERSEY LTD
DI CK IPA WIPES
Batch N : ENT 19214 13287
Batch N : ENT 19215 13287
D. EMERSY, 06.05.2013

The control of the applied radiation dose is done by Synergy Health using Red Perspex dosimeters calibrated by the English National Physical Laboratory.

Synergy Health Marseille,

A. NOEL
Process Control Officer

S. LE GONIDEC
Quality Assistant

Certificate # 19038301 / 1

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accelerating drug development. exactly.

ECP Reçu le 25 AVR. 2013 N° 130422.06A

ANALYSIS REPORT
N° 97-095 - Page 1 / 3

printed on the 22 April 2013 by :

Charles River Laboratories
Laboratoire Endosafe – Bât E2
Domaine des Oncins
Boite postale 0109
69592 L'Arbresle Cedex, France

Tél. : +33 (0)4 74 01 69 32
Fax. : +33 (0)4 74 72 28 21

for customer n° 7669 :

ECP (Entegris Cleaning Process)
A l'attention de Mr Damien GHERSY
A l'attention de Mr Edouard LAFONT
395 rue Louis Lépine
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

18 april 2013

Testing date

19 april 2013

Number of samples

1

Product
Wipe pré-imbibées d'alcool isopropylique 70% (IPA)

Endotoxin limit (EP)
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 UI/mL
Product potency : NA
λ = Sensitivity : 0,005 IU/mL

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

cofrac
ESSAIS
ACCREDITATION
N° 1-1850
Scope available
on www.cofrac.fr

Operator
Marjorie ARRIVAT
Lab. technician

22 AVR. 2013

Quality Reviewer

Non Applicable cGMP

Technical Reviewer
Vanessa SAVOYE
Adjointe technique laboratoire

22 AVR. 2013

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Number of samples

1

Product
Wipe pré-imbibées d'alcool isopropylique 70% (IPA)

Endotoxin limit (EP)
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

Paquet de IPA Wipe

Operational Conditions

cut the extremity of the bag and twist to the solution out. Dilution in LRW Water.
Using BG120 (Endotoxin Specific Buffer).

Dilution	pH *	Spike recovery**	Interference
1/1	7,1	NA	NA
1/10	7,1	2 %	Inhibitor
1/25	7,1	45 %	Inhibitor
1/50	7,1	89 %	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.

cofrac
ESSAIS
ACCREDITATION
N° 1-1850
Scope available
on www.cofrac.fr

Operator
Marjorie ARRIVAT
Lab. technician

Quality Reviewer

Non Applicable cGMP

Technical Reviewer

Vanessa SAVOYE
Adjointe technique laboratoire

22 AVR. 2013

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Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

18 april 2013

Testing date

19 april 2013

Number of samples

1

Product
Wipe pré-imbibées d'alcool isopropylique 70% (IPA)

Endotoxin limit (EP)
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
Paquet de IPA Wipe
Operational conditions
cut the extremity of the bag and twist to the solution out. Dilution 1/50 in LRW Water. Using BG120 (Endotoxin Specific Buffer).

Batch / Sample / Number	Endotoxin amount	Units
ENT19214 13 287	**< 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.

cofrac ESSAIS
ACCREDITATION
N° 1-1850
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Operator
Marjorie ARRIVAT
Lab. technician

22 AVR. 2013

Quality Reviewer

Non Applicable cGMP

Technical Reviewer

Vanessa SAVOYE
Adjointe technique laboratoire

22 AVR. 2013

ENTEGRIS CLEANING PROCESS
E C P
An Entegris Company

CONTROL REPORT

Diversey

Customer	Management Quality Manual n° MMMQ0000 (contractual)
DIVERSEY LTD	

Product : DI CK IPA WIPES VH42 12x25 PC	**Control report n°** : CERT 13103
Specification reference : NA	
Analyst : LGR	**Purchase order n° :** 4701288394
	Date of receipt : 03/19/2013

PHYSICAL AND CHEMICAL PROPERTIES CONTROL

Customer's batch n° : ENT19214 13 287	**ISOTRON certificate(s) n°** : NA
Date of manufacturing : 03/2013	**Produced quantity** : 360
Expiry date : 03/2015	**FIDT N°** : 1818 ind 0
ECP's batch n° : 19214	**Date of analysis** : 03/19/2013

Résultats :

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Specific gravity (base) (20°C)	IDT0301	0,870	0,865 - 0,875
Appearance (base) 20°C	NA	C	Clear, colourless liquid
Microbiological contagion of the EDI	IDT0236	9 UFC/ 100 mL	< 10 CFU /100mL

C : Conform NC : Not Conform
NA : Not Applicable

Batch released by
D. GHERSY, 06.05.2013

Conclusion : [X] CONFORM [ ] NOT CONFORM

Date : 03/25/2013	Written by : L.GRESSE	Checked by : D. GHERSY

P.O.

MedicalLab

Rapport N° / *Report N°*	**13/OI/STE/050**
Demandeur / *Sponsor*	*ECP* 395, rue Louis Lépine 34000 MONTPELLIER

Rapport d'essai - Essai de stérilité par la méthode de filtration sur membrane

Test report - Membrane filtration sterilty testing

selon la Pharmacopée Européenne 7e édition chapitre 2.6.1

according to the protocol 2.6.1 described into the seventh European Pharmacopoeia Edition

ECHANTILLON(S) - SAMPLES

Désignation : *Product name :*	IPA Wipe	Numéro de commande : *Order number :*	CF130377
Référence client : *Customer reference*	7519277	POE : *SIP :*	-
Numéro de lot : *Batch number :*	ENT19 214 13 287	Matériau(x) : *Material :*	-
Date de réception : *Receipt date :*	18 avril 2013	Donnée de stérilisation : *Sterilization data :*	-
Date de réalisation : *Testing date :*	18 avril 2013	Commentaire(s) : *Comment(s) :*	10 bidons poolés
Nombre d'échantillon(s) : *Sample quantity*	2		

PROTOCOLE - PROTOCOL

Volume d'échantillon : *Product tested volume :*	NA		
Solution neutralisante : *Neutralizing solution :*	DNP + Thiosulfate	Volume de rinçage : *Rinsing volume*	3 x 100 ml
Nombre de milieux testés : *Tested media quantity :*	2	Volume d'immersion de la membrane : *Immersion volume of membranes*	100 ml

Conditions *Conditions*	Milieux de culture *Media*	Température d'incubation *Incubation temperature*	Durée d'incubation *Incubation period*
Bactéries aérobies, levures, champignons *Aerobic and fungal*	Bouillon Trypcase Soja *Tryptone soy solution*	22,5 ± 2,5°C	14 jours *14 days*
Bactéries anaérobies et aérobies *Anaerobic and aerobic*	Bouillon Thioglycolate avec Résazurine *Thioglycolate Resazurine solution*	32,5 ± 2,5°C	14 jours *14 days*

Validation de la méthode *Method validation* : 09/OI/VAL.STE/015

RESULTATS - RESULTS

Conditions / Milieux de culture *Conditions / Media*	Examen de la croissance microbienne du milieu *Assessment of the media microbian development*			
	Après 7 jours *After 7 days*		Après 14 jours *After 14 days*	
Bactéries aérobies, levures et moisissures / Bouillon Trypcase Soja *Aerobic and fungal / Tryptone soy solution*	-	Positifs *positive*	0	Positifs *positive*
	-	Négatifs *negative*	1	Négatifs *negative*
Bactéries anaérobies et aérobies / Bouillon Thioglycolate avec Résazurine *Anaerobic and aerobic / Thioglycolate Resazurine solution*	-	Positifs *positive*	0	Positifs *positive*
	-	Négatifs *negative*	1	Négatifs *negative*

CONTRÔLES - CONTROLS

	Avant (Before)	Après (After)
Contrôle plan de travail (UFC) *Work plan control (CFU)*	0	0
Air sous flux laminaire (UFC) *Laminar flow air control (CFU)*	0	

Contrôle de gant (UFC) *Glove control (CFU) :*	0
Contrôle stérilité milieux *Media sterility control :*	Conforme

CONCLUSION - CONCLUSION

Les échantillons testés ne présentent pas de croissance microbienne après 14 jours d'incubation

Tested products doesn't shown any microbian development after 14 days of incubation

Aucun produit ne s'est révélé positif lors de cet essai.

No *product was positive during the test*

Rédigé par : *Redact by :* DORAND Justine

Approuvé par : *Approved by* MARTINHO Alice
Ingénieur Biologiste

Date : vendredi 3 mai 2013

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MedicalLab

Microbiological and physico-chemical analysis - process validation
EN ISO 13485 (2003)

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03 MAI 2013
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