ENTEGRIS CLEANING PROCESS
E C P
An Entegris Company

CONTROL REPORT

Customer	Management Quality Manual n° MMMQ0000 (contractual)
JOHNSON Diversey LTD	

Product : ClearKlens DE VH29 70%	**Control report n° :** CERT 9429
Specification reference : NA	
Analyst : LGR	**Purchase order n° :** 4700741776
	Date of receipt : 22/12/2008

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT 05107 08 357	**ISOTRON certificate n° :** 13404301
Date of manufacturing : 22/12/2008	**Produced quantity :** 167 x 5L
Expiery date : 22/12/2010	**FIDT N° :** FIDT 1815 0
ECP's batch n° : 05107	**Date of analysis :** 22/12/08

Résultats :

Analyzed characteristics	Method of analysis	State in the production				Specification
		Beginning	middle 1	middle 2	end	
Appearance 20°C	NA	C	NA	NA	NA	Clear, colourless liquid
Smell	NA	C	NA	NA	NA	Slightly perfumed
Specific gravity (20°C)	IDT0301	0,889	NA	NA	NA	0,872 - 0,896
pH (20°C)	IDT0306	6,0	NA	NA	NA	6,0 - 9,0
Microbiological contagion of the EDI	IDT0236	< 1 UFC/100 mL	NA	NA	NA	< 10 cfu/100mL

C : Conform NC : Not Conform

NA : Not Applicable

Conclusion : [X] CONFORM [ ] NOT CONFORM

Date : 22/12/08	Edited: L. GRESSE	Checked: F. GAYRAUD	Approved : C. GARY

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.
MIN 712
13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le
13 OCT. 2008
N° 08101306A

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

- the specification of treatment # 224503P
- The requirements of the European Pharmacopoeia
- the results of the dosemapping # 110505 of 30/03/2006

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

Customer	:	**ECP ENTEGRIS CLEANING PROCESS**
Product	:	KITS BIDONS 5l
Customer's reference	:	Order # CF 080037 of 26/08/08
Quantity	:	4 pallets
Irradiation date	:	2008.08.27
Irradiation dose	:	21.1 kGy to 27.4 kGy
Irradiation batch number	:	13404301

CLEARKLENS DE VH29 70°6
Batch = ENT05107 08357
Date of manufacturing = 22/12/2008
Expiry date = 22/12/2010

F. COURTOIS 30/11/2009

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

Isotron France S.A.S.,

S. LE GONIDEC
Production Assistant

C. SIMONIN
Quality Assistant

ENTEGRIS CLEANING PROCESS
ECP
An Entegris Company
395, Rue Louis Lépine 34000 MONTPELLIER
Tel. +33 (0)4 67 22 43 95 - Fax +33 (0)4 67 22 [illegible] 90
info@ecp-entegris.com
www.ecp-entegris.com
443 196 980 RCS Montpellier TVA FR 55 443 196 980

SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

26, rue du Neufbourg - 57000 METZ
Dr Corinne GUITTON-BAERMANN
Médecin Biologiste
Tél : 03 87 74 30 56
Fax : 03 87 74 08 64
Mail :labms.barbier@bio-avenir.fr
Site Internet : http://www.saih.fr

ENTEGRIS
Mr VEYRUNES
395, Rue LOUIS LEPINE
34000 MONTPELLIER

ECP Reçu le
16 JAN. 2009
N° 09011601J

Dossier n°081231.40

Metz, le 14.01.09

TEST REPORT
ESSAY OF STERILITY

According to the « sterility » protocol described into the fifth Europeen Pharmacopee Edition Addendum 2000

Laboratory which carried out the test

Laboratory SAIH 26, rue de Neufbourg 57000 METZ, FRANCE

Complete identification of the sample

Name of the product	CLEARKLENS DE VH29
.....	(4 plastic packs of 5 liters)
Number of lot.....	ENT 051 07 08 357 Date of péremption : 22/12/2010
Manufacturer	JOHNSON DIVERSEY
Storage conditions.....	Original plastic pack, ambient temperature, out of the light

Method and validation

Method.....	Filtration on membranes
Rinsing liquid	sterile Trypton salt +0,5% Tween 80
Membranes.....	Nitrat of cellulose (porosity 0.45 micron) diameter 47 mm. Each unit is sterile SARTORIUS N° de lot : 0208114060703823

SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

SAIH

26, rue du Neufbourg - 57000 METZ
Dr Corinne GUITTON-BAERMANN
Médecin Biologiste
Tél : 03 87 74 30 56
Fax : 03 87 74 08 64
Mail :labms.barbier@bio-avenir.fr
Site Internet : http://www.saih.fr

Experiment conditions

Analysis period ..... du 31/12/08 au 14/01/09
Category 1
Strains ..... Staphylococcus aureus CIP 4-83
Bacillus subtilis CIP 52-62
Pseudomonas aeruginosa CIP 82-48
Clostridium sporogenes CIP 79-03
Candida albicans CIP 1180-79
Aspergillus niger ATCC 16404

Verification of the method and validation

Strains	Number of viable cells (UFC/ml)					
	Bacterial and fungal Suspension of essay (N)	test of growth			Witness of filtration (Nx)	Essay of filtration (Ny)
		Nv	Schaedler Solution	Casein Soja Solution		
Staphylococcus aureus	$4,2 \times 10^8$	$2,5 \times 10^3$	+	+	$2,4 \times 10^3$	$2,4 \times 10^3$
Bacillus subtilis	$3,3 \times 10^8$	$1,8 \times 10^3$	+	+	$2,0 \times 10^3$	$1,9 \times 10^3$
Pseudomonas aeruginosa	$2,8 \times 10^8$	$1,9 \times 10^3$	+	+	$1,8 \times 10^3$	$1,6 \times 10^3$
Clostridium sporogenes	$3,5 \times 10^8$	$2,0 \times 10^3$	+	/	$2,1 \times 10^3$	$2,2 \times 10^3$
Candida albicans	$3,5 \times 10^7$	$2,0 \times 10^3$	/	+	$1,9 \times 10^3$	$1,8 \times 10^3$
Aspergillus niger	$1,6 \times 10^7$	$0,6 \times 10^3$	/	+	$0,7 \times 10^3$	$0,6 \times 10^3$

For the strains of the test :
N value must be between $1,5 \times 10^8$UFC/ml et 5×10^8UFC/ml for bacterial strains ;
N value must be between $1,5 \times 10^7$UFC/ml et 5×10^7UFC/ml for fungal strains ;
N_v value must be between 6×10^2UFC/ml et 3×10^3UFC/ml ;
N_x value must be over or equal at $0,5 \times N_v$ $N_x \approx N_y$
Ny value must be over or equal at $0,5 \times N_v$

The method is valid for the strains

SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

26, rue du Neufbourg - 57000 METZ
Dr Corinne GUITTON-BAERMANN
Médecin Biologiste
Tél : 03 87 74 30 56
Fax : 03 87 74 08 64
Mail :labms.barbier@bio-avenir.fr
Site Internet : http://www.saih.fr

Sterility control of the environmental growth solutions

Environmental growth solutions	incubation of temperature ± 1°C	After 14 days of incubation
Schaedler Solution	31°C	None bacterial or fugal developpement
Casein Soja Casein Soja Solution	31°C	None bacterial or fugal developpement
	24°C	None bacterial or fugal developpement

Results of essay

After 14 days of incubation	Total aerobic flore at 31°C ± 1°C	Total anaérobic flore at 31°C ± 1°C	Fungal flore at 24°C ± 1°C
Essai 1	0	0	0
Essai 2	0	0	0
Essai 3	0	0	0

Conclusion

According to the fifth Europeen Pharmacopee Edition Addendum 2000,the product CLEARKLENS DE VH29 (4 plastic flasks of 5 liters) ENT 051 07 08 357 Date of peremption : 22/12 /2010 doesn't shown any microbian development after 14 days of incubation into recommanded conditions.

Metz, 14/01/2009

The Biologist
Corinne GUITTON-BAERMANN

SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

26, rue du Neufbourg - 57000 METZ
Dr Corinne GUITTON-BAERMANN
Médecin Biologiste
Tél : 03 87 74 30 56
Fax : 03 87 74 08 64
Mail :labms.barbier@bio-avenir.fr
Site Internet : http://www.saih.fr

ENTEGRIS
Mr VEYRUNES
395 Rue Louis Lépine
34000 MONTPELLIER

Dossier n° 081231.40

Metz, le 14/01/2009

Packaging

Paperboard packages.....	OK
Closing mechanism	OK
Plastic packs.....	OK

charles river
accelerating drug development. exactly.

ECP Reçu le
30 JAN. 2009
N° 09013006 A

ANALYSIS REPORT
N° 58-036-2 UK - Page 1 / 5

printed on the 30 January 2009 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 Mr PORTEFAIX Jérôme
395 rue Louis Lépine
34000 MONTPELLIER

BACTERIAL ENDOTOXINS TEST
including test for interfering factors using 3 batches

Technical Contract

Technical questionnaire

Method

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

24 december 2008

Testing date

14 january 2009

Number of samples

2

Product
ClearKlens

Endotoxin limit (Entegris)
0,25 UI/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 : /
λ = Sensitivity : 0,005 IU/mL

$$\mathbf{DMS} = \frac{0{,}25\ \text{UI/ml}}{0{,}005\ \text{UI/mL}} = \mathbf{50}$$

cofrac
ESSAIS
ACCREDITATION
N° 1-1850
Portée disponible
sur www.cofrac.fr

Operator :
Fanny MORI
Lab. Technician
30 JAN. 2009

Reviewer :
Gilles GOY
Responsable Technique Laboratoire
30 JAN. 2009

charles river
accelerating drug development. exactly.

ANALYSIS REPORT
N° 58-036-2 UK - Page 2 / 5

printed on the 30 January 2009 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 Mr PORTEFAIX Jérôme
395 rue Louis Lépine
34000 MONTPELLIER

BACTERIAL ENDOTOXINS TEST
including test for interfering factors using 3 batches

Technical Contract

Technical questionnaire

Method

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

24 december 2008

Testing date

14 january 2009

Number of samples

2

Product
ClearKlens

Endotoxin limit (Entegris)
0,25 UI/ml

2. Test for Interfering Factors Batch 1

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 DE Lot ENT03956 08 267

Conditions opératoires

Dilution in LRW (LAL reagent water)

Dilution	pH *	Spike recovery**	Interference
1/1	7,1	NA	NA
1/5	7,1	NA	NA
1/10	7,1	23%	Inhibition
1/50	7,1	137%	No interference

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

The sample is interference free at 1/50.

Operator :
Fanny MORI
Lab. Technician

30 JAN. 2009

Reviewer :

Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009

cofrac
ESSAIS
ACCREDITATION
N° 1-1650
Portée disponible
sur www.cofrac.fr

ISO 9001:2000 SGS

charles river
accelerating drug development. exactly.

ANALYSIS REPORT
N° 58-036-2 UK - Page 3 / 5

printed on the 30 January 2009 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 Mr PORTEFAIX Jérôme
395 rue Louis Lépine
34000 MONTPELLIER

BACTERIAL ENDOTOXINS TEST
including test for interfering factors using 3 batches

Technical Contract

Technical questionnaire

Method

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

24 december 2008

Testing date

14 january 2009

Number of samples

2

Product
ClearKlens

Endotoxin limit (Entegris)
0,25 UI/ml

2. Test for Interfering Factors Batch 2

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 DE Lot ENT05107 08 357

Conditions opératoires

Dilution in LRW (LAL reagent water)

Dilution	pH *	Spike recovery**	Interference
1/1	7,1	NA	NA
1/5	7,2	NA	NA
1/10	7,1	17%	Inhibition
1/50	7,1	118%	No interference

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

The sample is interference free at 1/50.

Operator :
Fanny MORI
Lab. Technician

30 JAN. 2009

Reviewer :
Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009

cofrac
ESSAIS
ACCREDITATION
N° 1-1650
Portée disponible
sur www.cofrac.fr

charles river
accelerating drug development, exactly.

ANALYSIS REPORT
N° 58-036-2 UK - Page 4 / 5

printed on the 30 January 2009 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 Mr PORTEFAIX Jérôme
395 rue Louis Lépine
34000 MONTPELLIER

BACTERIAL ENDOTOXINS TEST
including test for interfering factors using 3 batches

Technical Contract

Technical questionnaire

Method

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

24 december 2008

Testing date

14 january 2009

Number of samples

2

Product
ClearKlens

Endotoxin limit (Entegris)
0,25 UI/ml

2. Test for Interfering Factors Batch 3

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

N.A ; Pas de 3ème lot

Conditions opératoires

N.A

Dilution	pH *	Spike recovery**	Interference

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

cofrac
ESSAIS
ACCREDITATION
N° 1-1650
Portée disponible
sur www.cofrac.fr

Operator :
Fanny MORI
Lab. Technician

30 JAN. 2009

Reviewer :
Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009

charles river
accelerating drug development. exactly.

ANALYSIS REPORT
N° 58-036-2 UK - Page 5 / 5

printed on the 30 January 2009 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 Mr PORTEFAIX Jérôme
395 rue Louis Lépine
34000 MONTPELLIER

BACTERIAL ENDOTOXINS TEST
including test for interfering factors using 3 batches

Technical Contract

Technical questionnaire

Method

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

24 december 2008

Testing date

14 january 2009

Number of samples

2

Product
ClearKlens

Endotoxin limit (Entegris)
0,25 UI/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
Operational conditions
Dilution 1/50 in LRW (LAL reagent water)

batch / Sample / Number	Endotoxin amount	Units
CLEARKLENS DE - ENT 03956 08 267	< 0,25	UI/mL
CLEARKLENS DE - ENT 05107 08 357	< 0,25	UI/mL

cofrac
ESSAIS
ACCREDITATION
N° 1-1850
Portée disponible
sur www.cofrac.fr

Operator :
Fanny MORI
Lab. Technician

Reviewer :
Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009

30 JAN. 2009