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 9239
Specification reference : NA	
Analyst : JBU	**Purchase order n° :** 4700713568
	Date of receipt : 23/09/2008

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT03956 08 267	**ISOTRON certificate n° :** 13613901 (only for 48 bottles)
Date of manufacturing : 23/09/08	**Produced quantity :** 168 x 5L
Expiery date : 23/09/2010	**FIDT N° :** FIDT 1815 ind 0
ECP's batch n° : 03956	**Date of analysis :** 23/09/08

Résultats :

Analyzed characteristics	Method of analysis	State in the production				Specification
		Beginning	middle 1	middle 2	end	
Appearance 20°C	NA	C	C	C	C	Clear, colourless liquid
Specific gravity (20°C)	IDT0301	0,882	0,882	0,882	0,882	0,872 - 0,896
pH (20°C)	IDT0306	7,6	7,6	7,6	7,6	6,0 - 9,0
Microbiological contagion of the EDI	IDT0236	< 1 UFC/100mL	NA			< 10 cfu/100mL

C : Conform NC : Not Conform

NA : Not Applicable

Conclusion : [X] CONFORM [ ] NOT CONFORM

Date : 23/09/08	Edited: J. BURGOS	Checked: F. GAYRAUD	Approved : C. GARY

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

ECP Reçu le 30 JAN. 2009

N° 09013001A

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

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 Pharmacopea

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

Customer	:	**ECP ENTEGRIS CLEANING PROCESS**
Product	:	BOTTLES 5L CLEARKLENS OF 70%
Customer's reference	:	ORDER # CF 080640 OF 31/10/08
Quantity	:	12 CARTONS
Irradiation date	:	2008.11 05
Irradiation dose	:	28.8 kGy to 50.5 kGy
Irradiation batch number	:	13613901

CLEARKLENS DE V H29 70%
Batch = ENT 039 5608 267
for 48 bottles
Date of manufacturing = 23/09/08
Expiery date = 23/09/2010
F. COURTOIS 30/01/2009

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. DEFAZIO
Process Control

C. SIMONIN
Quality Assistant

Certificate # 13613901/2

The treatment of this batch was applied in two fractions

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 21 JAN. 2009 N° 09012101D

Dossier n°081121.30

Metz, le 05.12.08

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 039 56 08 267 Date of péremption : 23/09/2010
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 21/11/08 au 05/12/08
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	$3,9 \times 10^8$	$2,2 \times 10^3$	+	+	$2,1 \times 10^3$	$2,1 \times 10^3$
Bacillus subtilis	$3,9 \times 10^8$	$2,2 \times 10^3$	+	+	$2,2 \times 10^3$	$2,3 \times 10^3$
Pseudomonas aeruginosa	$2,5 \times 10^8$	$1,8 \times 10^3$	+	+	$1,9 \times 10^3$	$1,7 \times 10^3$
Clostridium sporogenes	$3,9 \times 10^8$	$2,2 \times 10^3$	+	/	$2,3 \times 10^3$	$2,1 \times 10^3$
Candida albicans	$3,8 \times 10^7$	$2,2 \times 10^3$	/	+	$2,3 \times 10^3$	$2,2 \times 10^3$
Aspergillus niger	$1,7 \times 10^7$	$0,8 \times 10^3$	/	+	$0,6 \times 10^3$	$0,8 \times 10^3$

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

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

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 039 56 08 267 Date of peremption : 23/09 /2010 doesn't shown any microbian development after 14 days of incubation into recommanded conditions.

Metz, 05/12/2008

The Biologist
Corinne GUITTON-BAERMANN

SAIH

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° 081121.30

Metz, le 05/12/2008

Packaging

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

charles river
accelerating drug development. exactly.

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° 1-1650
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 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

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° 1-1850
Portée disponible
sur www.cofrac.fr

ISO 9001:2000 SGS

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 B2
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

30 JAN. 2009

Reviewer :
Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009