

CONTROL REPORT

<u>Customer</u> JOHNSON DIVERSEY LTD	Management Quality Manual n° MMMQ0000 (contractual)
<u>Product</u> : Clearklens IPA VH1 70%	<u>Control report n°</u> : CERT 9200
<u>Specification reference</u> : NA	
<u>Analyst</u> : LGR	<u>Purchase order n°</u> : 4700713568
	<u>Date of receipt</u> : 04/09/2008

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

<u>Customer's batch n°</u> : ENT03686 08 248	<u>ISOTRON certificate n°</u> : 13409601
<u>Date of manufacturing</u> : 04/09/2008	<u>Produced quantity</u> : 108 x 5L
<u>Expiery date</u> : 04/09/2010	<u>FIDT N°</u> : FIDT 1814 0
<u>ECP's batch n°</u> : 03686	<u>Date of analysis</u> : 04/09/08

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	0,87	0,870	0,870	0,870	0,865 - 0,875
pH (20°C)	IDT0306	7,8	7,8	7,8	7,8	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 :

☒ CONFORM

☐ NOT CONFORM

Date : 04/09/08	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° 08101305A

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 dosimetry # 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 28/08/08

Quantity : 3 pallets

Irradiation date : 2008.08.29

Irradiation dose : 17.1 kGy to 23.6 kGy

Irradiation batch number : 13409601

ClearKlenz IPA VH1 70%

Batch = ENT0368608248

Date of manufacturing = 04/09/2008

Expiry date = 04/09/2010

F. COURTOIS 02/07/2009

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

ENTEGRIS CLEANING PROCESS



An Entegris Company

Isotron France S.A.S.,

S. LE GONIDEC

Production Assistant

C. SIMONIN

Quality Assistant

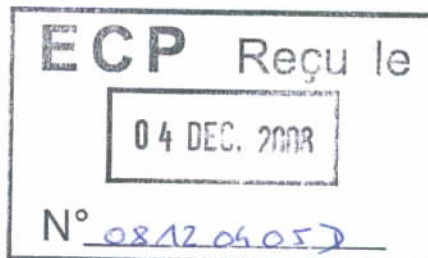
Certificate # 13409601 / 2

395, Rue Louis Léprieux 34000 MONTPELLIER
Tél. +33 (0)4 67 22 40 95 - Fax +33 (0)4 67 22 49 93
info@ecp-entegris.com
www.ecp-entegris.com
186 563 RCS Montpellier TVA FR 55 443 186 583



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

Dossier n° 081120.29

Metz, le 04.12.2008

TEST REPORT **ESSAY OF STERILITY**

*According to the « sterility » protocol described into the fifth European Pharmacopoe 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 IPA VH1
..... (4 plastic packs of 5 liters)
Number of lot ENT 036 86 08 248 Date of péremption : 04/09/2010
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

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 20/11/08 au 04/12/08
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		
<i>Staphylococcus aureus</i>	3,9 x 10 ⁸	2,1 x 10 ³	+	+	2,2 x 10 ³	2,1 x 10 ³
<i>Bacillus subtilis</i>	2,5 x 10 ⁸	1,1 x 10 ³	+	+	1,1 x 10 ³	1,2 x 10 ³
<i>Pseudomonas aeruginosa</i>	3,8 x 10 ⁸	2,3 x 10 ³	+	+	2,3 x 10 ³	2,4 x 10 ³
<i>Clostridium sporogenes</i>	3,5 x 10 ⁸	2,3 x 10 ³	+	/	2,1 x 10 ³	2,0 x 10 ³
<i>Candida albicans</i>	4,4 x 10 ⁷	2,7 x10 ³	/	+	2,6 x 10 ³	2,5 x 10 ³
<i>Aspergillus niger</i>	1,8 x 10 ⁷	0,8 x 10 ³	/	+	0,8 x 10 ³	0,6 x 10 ³

For the strains of the test :

N value must be between $1,5 \times 10^8$ UFC/ml et 5×10^8 UFC/ml for bacterial strains ;

N value must be between $1,5 \times 10^7$ UFC/ml et 5×10^7 UFC/ml for fungal strains ;

N_v value must be between 6×10^2 UFC/ml et 3×10^3 UFC/ml ;

N_x value must be over or equal at $0,5 \times N_v$ N_x $\neq$ N_y

N_y 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 $\pm 1^{\circ}\text{C}$	After 14 days of incubation
Schaedler Solution	31°C	None bacterial or fungal developpement
Casein Soja Casein Soja Solution	31°C	None bacterial or fungal developpement
	24°C	None bacterial or fungal developpement

Results of essay

After 14 days of incubation	Total aerobic flore at 31°C $\pm 1^{\circ}\text{C}$	Total anaérobic flore at 31°C $\pm 1^{\circ}\text{C}$	Fungal flore at 24°C $\pm 1^{\circ}\text{C}$
Essai 1	0	0	0
Essai 2	0	0	0
Essai 3	0	0	0

Conclusion

According to the fifth European Pharmacopee Edition Addendum 2000, the product CLEARKLENS IPA VH1 (4 plastic flasks of 5 liters) ENT 036 86 08 248 Date of peremption : 04/09 /2010 doesn't shown any microbial development after 14 days of incubation into recommended conditions.

Metz, 04/12/2008

**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>

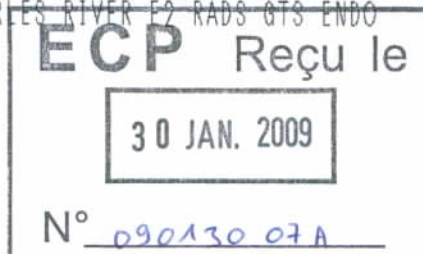
ENTEGRIS
Mr VEYRUNES
395 Rue Louis Lépine
34000 MONTPELLIER

Dossier n° 081120.29

Metz, le 04/12/2008

Packaging

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



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 1 batch

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

1

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 :

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

With :

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

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

cofrac



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



Operator :
Fanny MORI
Lab. Technician

30 JAN. 2009

endotoxin and microbial detection
BP 109 - 69592 L'Arbresle Cedex, France

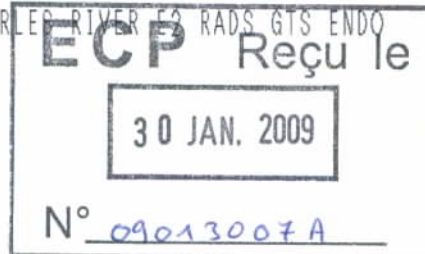
Tel: 00 800 15 78 97 43 • Fax: 00 33 474 01 65 31 • Email: euendo@eu.crl.com • www.criver.com

Charles River Laboratories France S.A.S. • Capital: 69 969 360 € • VAT No. FR 29 086 650 041 • SIRET: 086 850 041 00022 • APE: 7218Z

Reviewer :

Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009



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 1 batch

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

1

Product

ClearKlens

Endotoxin limit (Entegris)

0,25 UI/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 Lot ENT03686 08 248

Conditions opératoires

Dilution in LRW (LAL reagent water)

<u>Dilution</u>	<u>pH *</u>	<u>Spike recovery**</u>	<u>Interference</u>
1/1	7,1	NA	NA
1/5	7,1	NA	NA
1/10	7,2	5%	Inhibition
1/50	7,1	95%	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

Reviewer :

Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009 endotoxin and microbial detection
BP 109 - 69592 L'Arbresle Cedex, France

Tel: 00 800 15 78 97 43 • Fax: 00 33 474 01 65 31 • Email: eurendo@eu.crl.com • www.criver.com

Charles River Laboratories France S.A.S. • Capital: 69 969 360 € • VAT No. FR 29 086 650 041 • SIRET: 086 650 041 00022 • APE: 7219Z

cofrac



ESSAIS

ACCREDITATION
N° 1-1850

Portée disponible
sur www.cofrac.fr



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 1 batch

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

1

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

CLEARKLENS IPA - ENT 03686 08248

Endotoxin amount Units

< 0,25 UI/mL

cofrac



ESSAIS

ACCREDITATION
N° 1-1950
Portée disponible
sur www.cofrac.fr



Operator :

Fanny MORI
Lab. Technician

30 JAN. 2009

endotoxin and microbial detection

BP 109 - 69592 L'Arbresle Cedex, France

Tel: 00 800 15 78 97 43 • Fax: 00 33 474 01 65 31 • Email: eurendo@eu.crl.com • www.criver.com

Charles River Laboratories France S.A.S. • Capital: 69 969 360 € • VAT No. FR 29 086 650 041 • SIRET: 086 650 041 00022 • APE: 7219Z

Reviewer :

Gilles GOY
Responsable Technique Laboratoire

30 JAN. 2009