

CONTROL REPORT

Customer JOHNSON Diversey LTD	Management Quality Manual n° MMMQ0000 (contractual)
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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 : ☒ CONFORM ☐ NOT CONFORM

Date : 23/09/08

Edited: J. BURGOS

Checked: F. GAYRAUD

Approved: C. GARY

IMP 0180 - L

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

CLEARKLENS DE V H29 70%

Irradiation date : 2008.11.05

Irradiation dose : 28.8 kGy to 50.5 kGy

Batch = ENT0395608267
for 48 bottles

Date of manufacturing = 23/09/08
Expiry date = 23/09/2010

Irradiation batch number : 13613901

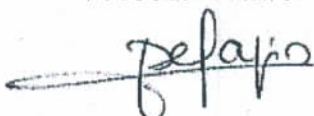
F. COURTOIS 30/01/2009
curator

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



Certificate # 13613901/2

The treatment of this batch was applied in two fractions

C. SIMONIN

Quality Assistant



ENTEGRIIS CLEANING PROCESS

ECP

An Entegris Company

395, Rue Louis Léprie 34000 MONTPELLIER

Tel +33 (0)4 67 22 40 95 - Fax +33 (0)4 67 22 40 90

info@ecp-entegris.com

ecp-entegris.com

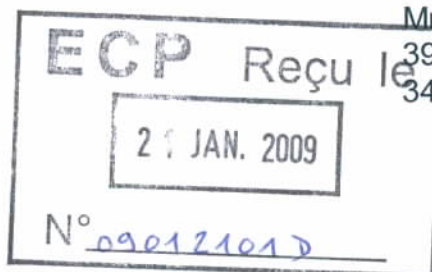
TVA FR 55 443 505 580



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°081121.30

Metz, le 05.12.08

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 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



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Fax : 03 87 74 08 64
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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		
<i>Staphylococcus aureus</i>	$3,9 \times 10^8$	$2,2 \times 10^3$	+	+	$2,1 \times 10^3$	$2,1 \times 10^3$
<i>Bacillus subtilis</i>	$3,9 \times 10^8$	$2,2 \times 10^3$	+	+	$2,2 \times 10^3$	$2,3 \times 10^3$
<i>Pseudomonas aeruginosa</i>	$2,5 \times 10^8$	$1,8 \times 10^3$	+	+	$1,9 \times 10^3$	$1,7 \times 10^3$
<i>Clostridium sporogenes</i>	$3,9 \times 10^8$	$2,2 \times 10^3$	+	/	$2,3 \times 10^3$	$2,1 \times 10^3$
<i>Candida albicans</i>	$3,8 \times 10^7$	$2,2 \times 10^3$	/	+	$2,3 \times 10^3$	$2,2 \times 10^3$
<i>Aspergillus niger</i>	$1,7 \times 10^7$	$0,8 \times 10^3$	/	+	$0,6 \times 10^3$	$0,8 \times 10^3$

For the strains of the test :

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



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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 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 microbial development after 14 days of incubation into recommanded conditions.

Metz, 05/12/2008

**The Biologist
Corinne GUITTON-BAERMANN**



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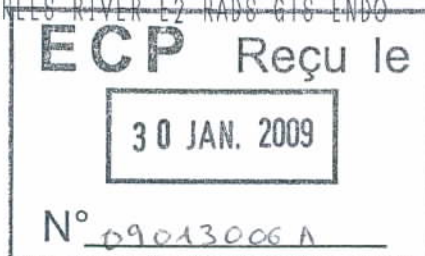
ENTEGRIS
Mr VEYRUNES
395 Rue Louis Lépine
34000 MONTPELLIER

Dossier n° 081121.30

Metz, le 05/12/2008

Packaging

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



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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 :

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

With :

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

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



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

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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

Reviewer :

Gilles GOY
Responsable Technique Laboratoire

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ACCREDITATION

N° 1-1850

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Boîte postale 0109
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Tél. : +33 (0)4 74 01 69 32
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Method

Method D Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

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Testing date

14 january 2009

Number of samples

2

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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)

<u>Dilution</u>	<u>pH *</u>	<u>Spike recovery**</u>	<u>Interference</u>
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

Reviewer :

Gilles GOY

Responsable Technique Laboratoire

30 JAN. 2009

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Domaine des Oncins
Boîte postale 0109
69592 L'Arbresle Cedex, France

Tél. : +33 (0)4 74 01 69 32

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including test for interfering factors using 3 batches

Technical ContractTechnical questionnaireMethod

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**DilutionpH *Spike recovery**Interference

* : pH must be within 6 and 8

** : spike recovery must be within 50% and 200 %

Operator :**Fanny MORI****Lab. Technician**Reviewer :**Gilles GOY****Responsable Technique Laboratoire****30 JAN. 2009****endotoxin and microbial detection**

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Laboratoire Endosafe - Bât E2
Domaine des Oncins
Boite postale 0109
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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

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Operator :

Fanny MORI

Lab. Technician

Reviewer :

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