

CONTROL REPORT

Customer JOHNSON Diversey LTD		Management Quality Manual n° MMMQ0000 (contractual)	
Product : ClearKlens DE VH29 70%		Control report n° : CERT 9429	
Specification reference : NA		Purchase order n° : 4700741776	
Analyst : LGR		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 :☒

CONFORM

☐

NOT CONFORM

Date : 22/12/08	Edited: L. GRESSE	Checked: F. GAYRAUD	Approved: C. GARY
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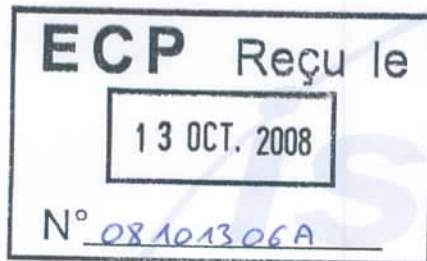
CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

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 # 224503P
- The requirements of the European Pharmacopoeia
- the results of the dose mapping # 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

CLEAR KLÉNS DE VH29 70%

Batch = ENT05107 08357

Date of manufacturing = 22/12/2008

Expiry date = 22/12/2010

F. COURTOIS 30/08/2009

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

Certificate # 13404301 / 2

C. SIMONIN

Quality Assistant

ENTEGRISS CLEANING PROCESS



An Entegris Company

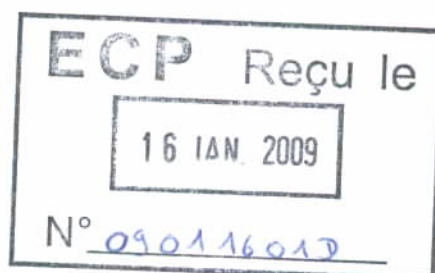
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SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

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ENTEGRIS
Mr VEYRUNES
395, Rue LOUIS LEPINE
34000 MONTPELLIER



Dossier n°081231.40

Metz, le 14.01.09

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 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



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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		
<i>Staphylococcus aureus</i>	4,2 x 10 ⁸	2,5 x 10 ³	+	+	2,4 x 10 ³	2,4 x 10 ³
<i>Bacillus subtilis</i>	3,3 x 10 ⁸	1,8 x 10 ³	+	+	2,0 x 10 ³	1,9 x 10 ³
<i>Pseudomonas aeruginosa</i>	2,8 x 10 ⁸	1,9 x 10 ³	+	+	1,8 x 10 ³	1,6 x 10 ³
<i>Clostridium sporogenes</i>	3,5 x 10 ⁸	2,0 x 10 ³	+	/	2,1 x 10 ³	2,2 x 10 ³
<i>Candida albicans</i>	3,5 x 10 ⁷	2,0 x10 ³	/	+	1,9 x 10 ³	1,8 x 10 ³
<i>Aspergillus niger</i>	1,6 x 10 ⁷	0,6 x 10 ³	/	+	0,7 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 $0,5 \times N_v$ $N_x \approx N_y$

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 development
Casein Soja Casein Soja Solution	31°C	None bacterial or fungal development
	24°C	None bacterial or fungal development

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 Pharmacopée 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 microbial development after 14 days of incubation into recommended conditions.

Metz, 14/01/2009

The Biologist
Corinne GUITTON-BAERMANN



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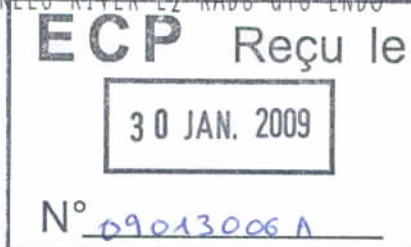
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Dossier n° 081231.40

Metz, le 14/01/2009

Packaging

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



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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

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

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Operator :

Fanny MORI

Lab. Technician

Reviewer :

Gilles GOY

Responsable Technique Laboratoire

30 JAN. 2009

endotoxin and microbial detection

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ECP (Entegris Cleaning Process)
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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)

<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	7,1	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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including test for interfering factors using 3 batches

Technical Contract

Product
ClearKlens

Endotoxin limit (Entegris)
0,25 UI/ml

Technical questionnaire

Méthod

Method D
Kinetic chromogenic

Sensitivity

0,005 IU/mL

Sample delivery date

24 december 2008

Testing date

14 january 2009

Number of samples

2

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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

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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

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

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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 :

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Lab. Technician

Reviewer :

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