

CONTROL REPORT

Customer JOHNSON DIVERSEY LTD		Management Quality Manual n° MMMQ0000 (contractual)	
Product : ClearKlens TEGO 2000 RTU VH25S		Control report n° : CERT 9211	
Specification reference : NA		Purchase order n° : 4700713568	
Analyst : LGR		Date of receipt : 09/09/2008	

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT03776 08 253	ISOTRON certificate n° : 13409601, 13404301
Date of manufacturing : 09/09/2008	Produced quantity : 108 x 5L
Expiery date : 09/09/2009	FIDT N° : FIDT 1813 0
ECP's batch n° : 03776	Date of analysis : 09/09/2008

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 liquid
Specific gravity (20°C)	IDT0301	1,000	1,000	1,000	1,000	0,980 - 1,000
pH (20°C)	IDT0306	7,6	7,6	7,6	7,6	7,3 - 8,2
Microbiological contagion of the EDI	IDT0236	< 1 cfu/100mL	NA			< 10 cfu/100mL

C : Conform NC : Not Conform

NA : Not Applicable

Conclusion :☒ CONFORM☐ NOT CONFORM

Date : 09/09/08

Edited: L. GRESSE

Checked: F. GAYRAUD

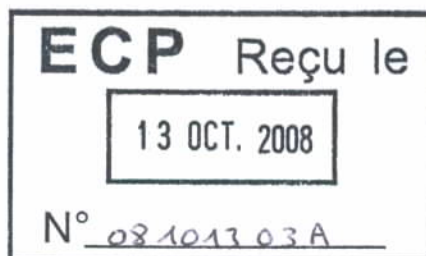
Approved: C. GARY

IMP 0180 - L



SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

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ENTEGRIS
Mr VEYRUNES
395, Rue LOUIS LEPINE
34000 MONTPELLIER

Dossier n° 080918.19

Metz, le 02.10.08

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 TEGO
..... (4 plastic packs of 5 liters)
Number of lot ENT 037 76 08 253 Date of péremption : 09/09/2009
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 18/09/08 au 02/10/08
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	Essay of filtration
		Nv	Schaedler Solution	Casein Soja Solution	(Nx)	(Ny)
<i>Staphylococcus aureus</i>	$3,9 \times 10^8$	$2,0 \times 10^3$	+	+	$2,2 \times 10^3$	$2,3 \times 10^3$
<i>Bacillus subtilis</i>	$3,5 \times 10^8$	$2,1 \times 10^3$	+	+	$2,2 \times 10^3$	$2,1 \times 10^3$
<i>Pseudomonas aeruginosa</i>	$3,6 \times 10^8$	$2,3 \times 10^3$	+	+	$2,1 \times 10^3$	$2,1 \times 10^3$
<i>Clostridium sporogenes</i>	$3,7 \times 10^8$	$2,1 \times 10^3$	+	/	$2,1 \times 10^3$	$2,1 \times 10^3$
<i>Candida albicans</i>	$3,7 \times 10^7$	$2,3 \times 10^3$	/	+	$2,1 \times 10^3$	$2,3 \times 10^3$
<i>Aspergillus niger</i>	$1,6 \times 10^7$	$0,9 \times 10^3$	/	+	$0,6 \times 10^3$	$0,6 \times 10^3$

For the strains of the test :

N value must be between $1,5 \times 10^8$ UFC/ml et 5×10^8 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 TEGO (4 plastic flasks of 5 liters) ENT 037 76 08 253 Date of peremption : 09/09 /2009 doesn't shown any microbial development after 14 days of incubation into recommanded conditions.

Metz, 02/10/2008

The Biologist
Corinne GUITTON-BAERMANN



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Dossier n° 080918.19

Metz, le 02/10/2008

Packaging

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

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 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

cleanKlens TEGO 2000 RTU VH255

Batch = ENT0377608253

Date of manufacturing = 09/09/2008

Expiry date = 09/09/2009

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

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° 081013 05 A

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

cleanKlens TEGO 2000 RTU VH255

Batch = ENT 03776 08253

Date of manufacturing = 09/09/2008

Expiry date = 09/09/2009

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 # 13409601 / 2

C. SIMONIN

Quality Assistant