

CONTROL REPORT

Customer JOHNSON Diversey LTD		Management Quality Manual n° MMMQ0000 (contractual)	
Product : Clearklens IPA VH1 70%		Control report n° : CERT 9532	
Specification reference : NA		Purchase order n° : 4700732791	
Analyst : LGR		Date of receipt : 16/02/2009	

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT 05744 09 047	ISOTRON certificate n° : 13404301 et 13798601
Date of manufacturing : 16/02/2009	Produced quantity : 167 x 5L
Expiry date : 02/2011	FIDT N° : FIDT 1814 C
ECP's batch n° : 05744	Dates of analysis : 16/02/09 - 05/03/09

Résultats :

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Appearance (base) 20°C	NA	C	Clear, colourless liquid
Specific gravity (base) (20°C)	IDT0301	0,871	0,865 - 0,875
pH (base) (20°C)	NA	8,7	6,0 - 9,0
Microbiological contagion of the EDI	IDT0236	< 1 UFC/100mL	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

The first pH result was not conform : value 10,5 (out of the range) -> Corrective action : FA n°1400 and DQ n°080923 02D, QP1.
A new measurement was performed at an external laboratory with a bench pH-meter : new value is 8,7 (conform to the specification range).
On March 16th, the customer accepted this batch (mail n°090331 04A).

Conclusion : ☒ CONFORM ☐ NOT CONFORM

Date : 01/04/09	Edited: D. CHEUNG	Checked: O. TASSART	Approved : P. PRE
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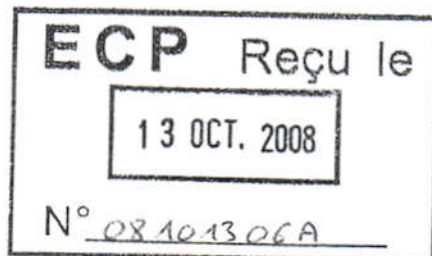
CERTIFICATE OF TREATMENT BY GAMMA RADIATION

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 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 26/08/08

Quantity : 4 pallets

Irradiation date : 2008.08.27

Irradiation dose : 21.1 kGy to 27.4 kGy

Irradiation batch number : 13404301

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

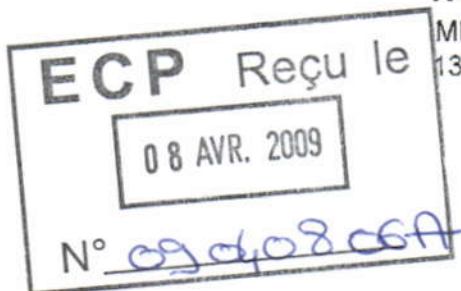
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- the results of the dose mapping # 110505 of 30/03/2006

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : 5I BOTTLE KIT

Customer's reference : ORDER # CF 080037 OF 13/01/09

Quantity : 4 PALLETS

Irradiation date : 2009.01.17

Irradiation dose : 18,1 kGy à 25,7 kGy

Irradiation batch number : 13798601

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.,

H. OSMAS

Process Control Officer

Certificate # 13798601 / 1

English translation of the french original certificate.

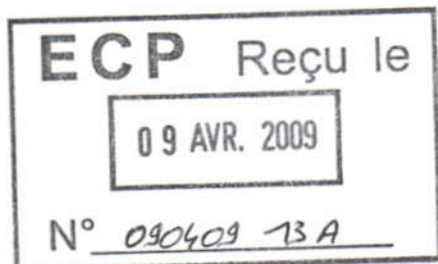
C. SIMONIN

Quality Assistant



SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

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ENTEGRIS
Mr VEYRUNES
395, Rue LOUIS LEPINE
34000 MONTPELLIER

Dossier n°090326.43

Metz, le 06.04.09

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 IPA 70%
..... (4 plastic packs of 5 liters)
Number of lot ENT 047 44 09 047 Date of péremption : 02/2011
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 26/03/09 au 06/04/09
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)					Witness of filtration (Nx)	Essay of filtration (Ny)
	Bacterial and fungal Suspension of essay (N)	test of growth					
		Nv	Schaedler Solution	Casein Soja Solution			
<i>Staphylococcus aureus</i>	4,3 x 10 ⁸	2,8 x 10 ³	+	+	2,7 x 10 ³	2,6 x 10 ³	
<i>Bacillus subtilis</i>	4,2 x 10 ⁸	2,6 x 10 ³	+	+	2,6 x 10 ³	2,5 x 10 ³	
<i>Pseudomonas aeruginosa</i>	3,5 x 10 ⁸	1,8 x 10 ³	+	+	1,8 x 10 ³	1,9 x 10 ³	
<i>Clostridium sporogenes</i>	3,7 x 10 ⁸	2,2 x 10 ³	+	/	2,2 x 10 ³	2,2 x 10 ³	
<i>Candida albicans</i>	3,7 x 10 ⁷	2,5 x10 ³	/	+	2,3 x 10 ³	2,4 x 10 ³	
<i>Aspergillus niger</i>	1,5 x 10 ⁷	0,5 x 10 ³	/	+	0,6 x 10 ³	0,5 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 ≈ 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 fugal developpement
Casein Soja Casein	31°C	None bacterial or fugal developpement
Soja Solution	24°C	None bacterial or fugal 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 IPA 70% (4 plastic flasks of 5 liters) ENT 057 44 09 047 Date of peremption : 02 /2011 doesn't shown any microbial development after 14 days of incubation into recommended conditions.

Metz, 06/04/2009

The Biologist
Corinne GUITTON-BAERMANN



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Dossier n° 090326.43

Metz, le 06/04/2009

Packaging

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

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pour le client / for customer n° : 7669

Charles River Laboratories

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ECP (Entegris Cleaning Process)
A l'attention Mr PORTEFAIX Jérôme
395 rue Louis Lépine
34000 MONTPELLIER

ESSAI DES ENDOTOXINES BACTERIENNES
Bacterial Endotoxins Test

Contrat Technique
Technical Contract

Questionnaire technique
Selon 58-036

Technique / Method

Méthode D
Colorimétrie cinétique

Sensibilité / Sensitivity

0,005 UI/mL

Date de réception
Simple delivery date

19 mars 2009

Date d'analyse
Testing date

20 mars 2009

Nbre d'échantillons
Number of samples

2

cofrac



ESSAIS
ACCREDITATION
N° 1-1850
Scope available
on cofrac.fr



Produit / Product
ClearKlens

Limite en endotoxines / Endotoxin limit (Entegris)
0,25 UI/ml

Les essais ont été réalisés en accord avec la Pharmacopée Européenne en vigueur, chapitre "2.6.14 – Endotoxines Bactériennes" harmonisé avec les Pharmacopées Américaine et Japonaise.

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.

ID produit / product ID
ClearKlens IPA 70% 5L

Lot / Prélèvement / Numéro
Batch / Sample / Number

ENT 05801 09 049

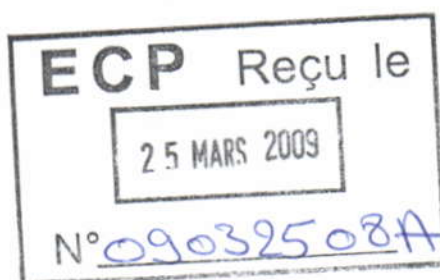
ENT 05744 09 047

Concentration en endotoxines
Endotoxin amount

Unités
Units

< 0,25 UI/mL

< 0,25 UI/mL



Opérateur / Operator
Fanny MORI
Technicienne de laboratoire / Lab. Technician

Approbateur / Reviewer
Vanessa SAVOYE
Technicienne de laboratoire

23 MARS 2009

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

23 MARS 2009

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