

CONTROL REPORT**Customer**

JOHNSON DIVERSEY LTD

Management Quality Manual n° MMMQ0000 (contractual)

Product :

Clearklens IPA VH1 70%

Control report n° :

CERT 9759

Specification reference :**Analyst :** LGR**Purchase order n° :**

4700806488

Date of receipt :

20/07/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES**Customer's batch n° :** ENT07274 09 196**ISOTRON certificate n° :** 14232101**Date of manufacturing :** 20/07/2009**Produced quantity :** 40 x 5L**Expiery date :** 07/2011**FIDT N° :** FIDT 1814 E**ECP's batch n° :** 07274**Date of analysis :** 20/07/2009**Résultats :**

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Appearance 20°C	NA	C	Clear, colourless liquid
Specific gravity (20°C)	IDT0301	0,870	0,865 - 0,875
pH (20°C)	NA	7,16	6,0 - 9,0
Microbiological contagion of the EDI	IDT0236	< 1 cfu/100mL	< 10 cfu/100mL

C : Conform NC : Not Conform

NA : Not Applicable

Conclusion :

CONFORM



NOT CONFORM

Date : 20/07/2009

Analyst : L. GRESSE

Checked : D. CHEUNG

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

Clear Blens IPA VH1 70°/6

Lot. ENT0727409 196

Date de fab: 2/07/09

Date de per. 07/2011

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : 5L BOTTLES KITS

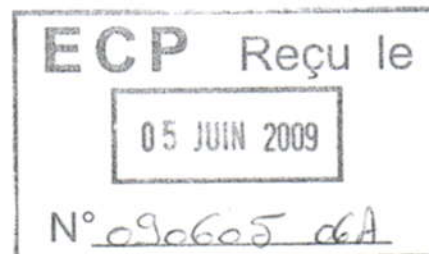
Customer's reference : ORDER # CF090074 OF 27/05/09

Quantity : 2 PALLETS

Irradiation date : 2009.05.31

Irradiation dose : 16.6 kGy to 23.2 kGy

Irradiation batch number : 14232101



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

A handwritten signature in black ink, appearing to be 'H. Osmas'.

Certificate # 14232101 / 1

C. SIMONIN

Quality Officer

A handwritten signature in black ink, appearing to be 'C. Simonin'.

Edité le / Printed on the : 27 juillet 2009, par / by :

pour le client / for customer n° : 7669

Charles River Laboratories

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Reçu le

/ 4 AOUT 2009

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

ENDO 90

Technique / Method

Méthode D
Colorimétrie cinétique

Sensibilité / Sensitivity

0,005 UI/mL

Date de réception
Simple delivery date

23 juillet 2009

Date d'analyse
Testing date

24 juillet 2009

Nbre d'échantillons
Number of samples

1

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.

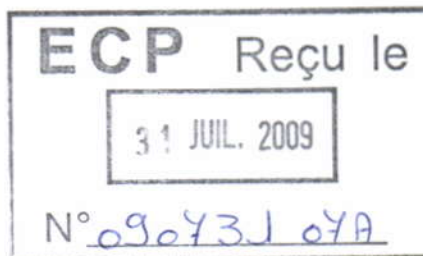
ID produit / product ID
ClearKlens IPA VH1 5L

Lot / Prélèvement / Numéro
Batch / Sample / Number

ENT 07274 09 196

Concentration en endotoxines Unités
Endotoxin amount Units

< 0,25 UI/mL



Opérateur / Operator
Sofiane SAIDI
Tech. de laboratoire / Lab. Technician

27 JUL. 2009

Approbateur Qualité / Quality Reviewer

Alexia DEVENS
Coordonateur Management Qualité

endotoxin and microbial detection

BP109 - 69592 L'Arbresle Cedex, France

Approbateur Technique / Technical Reviewer

Gilles GOY
Responsable Technique Laboratoire

29 JUL. 2009

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Report n° : **09/OI/STE/132**

Sponsor : **ECP**

395, rue Louis Léprie
34000 MONTPELLIER

Test report Essay of Sterility - Method filtration on membranes

According to the protocol 2.6.1 described into the sixth European Pharmacopoe Edition

TEST ARTICLE

Name of product : ClearKlens IPA VH1 Order number :
 Customer reference : 7516393 Internal reference :
 Batch number : ENT07 274 09 196 Material :
 Date of receipt : 23 juillet 2009 Date sterilization :
 Date of test : 24 juillet 2009 Comment(s) :
 Quantity of used sample : 10



PROTOCOL

Tested volume of product : **500** ml
 Neutralizing solution : **DNP + Thio** Rinsing volume : **3 x 100 ml**
 Number of media tested : **2** Immersion volume of membranes : **100 ml**

Conditions	Media	Incubation temperature	Time of incubation
Aerobic and fugal	Tryptone soy solution	22,5 ± 2,5°C	14 days
Anaerobic and aerobic	Thioglycolate Résazurine solution	32,5 ± 2,5°C	14 days

Method validation : **09/OI/VAL.STE/015**

RESULTS

Conditions	Assessment of the media turbidimetry			
	After 7 days		After 14 days	
Tryptone soy solution	0	positive	0	positive
	5	negative	5	negative
Thioglycolate Résazurine solution	0	positive	0	positive
	5	negative	5	negative

CONTROLS

Work plan control (before and after) :	0	0	Glove control :	Conforme
Air control :	0		Media sterility control :	Conforme

CONCLUSION

The tested product doesn't shown any microbial development after 14 days of incubation.

No product has been positive during the test.

Redact by : **MARTINHO Alice**

Ingénieur Biologiste

Approved by :

DRUTEL Dominique

Directeur Général MedicalLab

Date : **vendredi 7 août 2009**

Results and conclusion apply only on the test article tested. Any extrapolation of these data to other samples is the responsibility of the Sponsor.

MedicalLab

Microbiological and physico-chemical analysis - process validation
 EN ISO 13485 (2003)

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