

CONTROL REPORT**Customer**

JOHNSON Diversey LTD

Management Quality Manual n° MMMQ0000 (contractual)

Product :

Clearklens IPA VH1 70%

Control report n° :

CERT 9649

Specification reference :

NA

Analyst :

FGA

Purchase order n° :

4700732791

Date of receipt :

28/04/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES**Customer's batch n° :** ENT06292 09 104**ISOTRON certificate n° :** 14109801**Date of manufacturing :** 28/04/2009**Produced quantity :** 171 x 5L**Expiry date :** 04/2011**FIDT N° :** FIDT 1814 D**ECP's batch n° :** 06292**Date of analysis :** 28/04/09**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	0,865	0,865 - 0,875
pH (20°C)	NA	7,5	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 : 28/04/2009

Edited: L. GRESSE

Checked: F. GAYRAUD

Approved: C. GARY

IMP 0180 - L

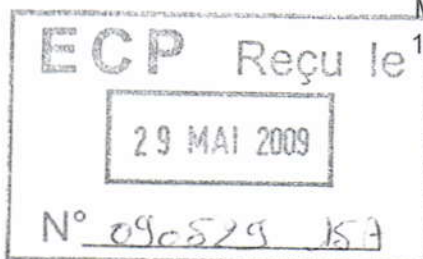
CERTIFICATE OF TREATMENT BY GAMMA RADIATION

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 : 5L BOTTLES KITS

Customer's reference : ORDER # CF090074 OF 17/04/09

Quantity : 2 PALLETS

Irradiation date : 2009.04.22

Irradiation dose : 20.0 kGy to 26.1 kGy

Irradiation batch number : 14109801

Clearance IPA VHJ 40 %

Lot ENT 06292 09 J04

Date fab: 28/04/09

Date pu: 04/2011

J. BURGOS R 29/06/09

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 # 14109801 / 1

English translation of the french original certificate.

C. SIMONIN

Quality Officer

Test report Essay of Sterility - Method filtration on membranes

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

TEST ARTICLE

Name of product :	ClearKlens IPA VH1	Order number :	CF090335
Customer reference :	7516393	Internal reference :	
Batch number :	ENT 06 292 09 104	Material :	
Date of receipt :	4 mai 2009	Date sterilization :	
Date of test :	4 juin 2009	Comment(s) :	début de production fin de production
Quantity of used sample :	2		

PROTOCOL

Tested volume of product :	500	ml	
Neutralizing solution :	DNP + Thiosulfate	Rinsing volume :	3 x 100 ml
Number of media tested :	2	Immersion volume of membranes :	90 ml

Conditions	Media	Incubation temperature	Time of incubation
Aerobic and fugal	Tryptone soy solution	20 ± 5°C	14 days
Anaerobic and aerobic	Thioglycolate Résazurine solution	30 ± 5°C	14 days

Fertility validation : **09/OI/VAL_FER/008**

RESULTS

Conditions	Assessment of the media turbidimetry			
	After 7 days		After 14 days	
Tryptone soy solution	0	positive	0	positive
	1	negative	1	negative
Thioglycolate Résazurine solution	0	positive	0	positive
	1	negative	1	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.

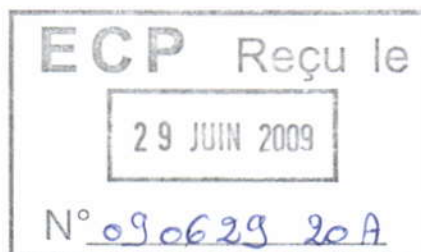
Redact by :	PEGOUD Céline Technicien Biologiste	Approved by :	MARTINHO Alice Ingénieur Biologiste
Date :	vendredi 26 juin 2009		

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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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
Sample delivery date

07 mai 2009

Date d'analyse
Testing date

07 mai 2009

Nbre d'échantillons
Number of samples

2

cofrac

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

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

07 MAI 2009

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Charles River France

Date : 11 mai 2009 Visa : 
endotoxin and microbial detection
BP 109 – 69592 L'Arbresle Cedex, France

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07 MAI 2009

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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

Concentration en endotoxines
Endotoxin amount

Unités
Units

ENT 06292 09 104

< 0,25 UI/mL

ENT 06426 09 118

< 0,25 UI/mL

