



CONTROL REPORT

Customer

JOHNSON Diversey LTD

Management Quality Manual n° MMMQ0000 (contractual)

Product :

Clearklens IPA VH1 70%

Control report n° :

CERT 9668

Specification reference :

NA

Analyst :

LGR

Purchase order n° :

4700783145

Date of receipt :

12/05/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT 06472 09 124

ISOTRON certificate n° : 14137301

Date of manufacturing : 12/05/2009

Produced quantity : 171 X 5L

Expiry date : 05/2011

FIDT N° : FIDT 1814 D

ECP's batch n° : 06472

Date of analysis : 12/05/09

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	9,0	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 : 12/05/09

Checked : D. CHEUNG

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

ECP Reçu le

25 MAI 2009

N° 090525 A

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 BOTTLE KIT

Customer's reference : ORDER # CF 090074 OF 24/04/09

Quantity : 2 PALLETS

Irradiation date : 2009.04.29

Irradiation dose : 19.2 kGy to 25.7 kGy

Irradiation batch number : 14137301

Reactions IPA 70% 52
Lot ENT06072 09124
Date fab. 12/05/09
Date per. 05/06/11

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 # 14137301 / 1

English translation of the french original certificate.

C. SIMONIN

Quality Officer



25 MAI 2009
N°

Edité le / Printed on the : 20 mai 2009, par / by :

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 Rev 1

Technique / Method

Méthode D
Colorimétrie cinétique

Sensibilité / Sensitivity

0,005 UI/mL

Date de réception
Simple delivery date

19 mai 2009

Date d'analyse
Testing date

19 mai 2009

Nbre d'échantillons
Number of samples

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

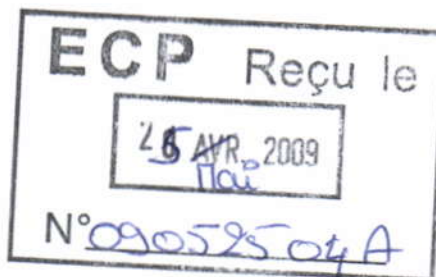
Lot / Prélèvement / Numéro
Batch / Sample / Number

ENT 06472 09 124

Concentration en endotoxines
Endotoxin amount

Unités
Units

< 0,25 UI/mL



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

20 MAI 2009

Approbateur Qualité / Quality Reviewer
Agnès DELACHAMBRE
Responsable Management Qualité
Charles River Laboratories France
Date : 20 Mai 2009

endotoxin and microbial detection

BP109 - 69592 L'Arbresle Cedex, France

Approbateur Technique / Technical Reviewer

Gilles GOY
Responsable Technique Laboratoire

20 MAI 2009

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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 :	ClearGens IPA VH1	Order number :	CF090335
Customer reference :	7516050	Internal reference :	-
Batch number :	ENT 06 472 09 124	Material :	-
Date of receipt :	14 mai 2009	Data sterilization :	-
Date of test :	4 juin 2009	Comment(s) :	fin de production milieu 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/011			

RESULTS

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

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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