ENTEGRIS CLEANING PROCESS
ECP
An Entegris Company

CONTROL REPORT

Customer	Management Quality Manual n° MMMQ0000 (contractual)
JOHNSON Diversey LTD	

Product : Clearklens IPA VH1 70%	**Control report n° :** CERT 9652
Specification reference : NA	
Analyst : LGR	**Purchase order n° :** 4700783145
	Date of receipt : 28/04/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT06426 09 118	**ISOTRON certificate n° :** 14109801
Date of manufacturing : 28/04/2009	**Produced quantity :** 171 x 5L
Expiery date : 04/2011	**FIDT N° :** FIDT 1814 D
ECP's batch n° : 06426	**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	0,874	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 : [X] CONFORM [ ] NOT CONFORM

Date : 28/04/2009	Edited: L. GRESSE	Checked: F. GAYRAUD	Approved : C. GARY

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.
MIN 712
13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le
29 MAI 2009
N° 090529 JSA

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 dosemapping # 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

Cleanklens IPA 70 %
Lot ENT 06426 09 M8
Date fab : 28/04/09
Date per : 04/2011

J. BURGOS le 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

C. SIMONIN
Quality Officer

Certificate # 14109801 / 1

English translation of the french original certificate.

charles river
accelerating drug development. exactly.

ECP Reçu le 12 MAI 2009 N° 090512 02A

RAPPORT D'ESSAI / *ANALYSIS REPORT*

N° 61-036 – Page / *Page* 1 / 1

Edité le / *Printed on the* : 7 mai 2009, par / *by* : pour le client / *for customer* n° : 7669

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Laboratoire Endosafe – Bât E2
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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

07 mai 2009

Date d'analyse
Testing date

07 mai 2009

Nbre d'échantillons
Number of samples

2

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**

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

Opérateur / *Operator*
Fanny MORI
Tech. de laboratoire / *Lab. Technician*
07 MAI 2009

Approbateur Qualité / *Quality Reviewer*
Alexia DEVENS
Coordinateur Management Qualité
Charles River France
Date : 11 mai 2009 Visa :

Approbateur Technique / *Technical Reviewer*
Vanessa SAVOYE
Technicienne de laboratoire
07 MAI 2009

MedicalLab

Report n° :	09/OI/STE/061
Sponsor :	ECP 395, rue Louis Lépine 34000 MONTPELLIER

Test report Essay of Sterility - Method filtration on membranes

According to the protocol 2.6.1 described into the sixth Europeen Pharmacopee Edition

TEST ARTICLE

Name of product :	ClearKlens IPA VH1	Order number :	CF090335
Customer reference :	7518050	Internal reference :	-
Batch number :	ENT 06 426 09 118	Material :	-
Date of receipt :	4 mai 2009	Data sterilization :	-
Date of test :	2 juin 2009	Comment(s) :	milieu de production 1/4 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/007

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
Air control :	0	

Glove control :	Conforme
Media sterility control :	Conforme

CONCLUSION

The tested product doesn't shown any microbian 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 Reçu le
29 JUIN 2009
N° 090629 J9A