ENTEGRIS CLEANING PROCESS
E C P
An Entegris Company

CONTROL REPORT

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

Product :		**Control report n° :**	CERT 9615
ClearKlens DE VH29 70%			
Specification reference :	NA		
Analyst :	LGR	**Purchase order n° :**	4300244459
		Date of receipt :	31/03/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT06165 09 091	**ISOTRON certificate n° :** 13951601
Date of manufacturing : 03/2009	**Produced quantity :** 160 x 5L
Expiery date : 03/2011	**FIDT N° :** FIDT 1815 0
ECP's batch n° : 06165	**Date of analysis :** 01/04/09

Résultats :

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Appearance 20°C	NA	C	Clear, colourless liquid
Smell	NA	C	Slightly perfumed
Specific gravity (20°C)	IDT0301	0,883	0,872 - 0,896
pH (20°C)	NA	9,0	6,0 - 9,0
Microbiological contagion of the EDI	IDT0236	< 1 UFC/100 mL	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion : [X] CONFORM [ ] NOT CONFORM

Date : 01/04/09	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 11 A

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	:	1L & 5L BOTTLES KITS
Customer's reference	:	ORDER # CF 090074 OF 20/02/09
Quantity	:	4 PALLETS
Irradiation date	:	2009.03.07
Irradiation dose	:	16.1 kGy to 25.0 kGy
Irradiation batch number	:	13951601

Cleanlens DE VH29
lot ENT 06J65 09 09 J
Date fab: 03/2009
Date exp: 03/2011

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 # 13951601 / 1
English translation of the french original certificate.

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CERTIFICATE OF ANALYSIS

Mr W Grayson

Johnson Diversy UK Limited
Osier Drive
Sherwood Park
Annesley NG15 0DS

Date Received	:	08-Apr-09
Date Tested	:	09-Apr-09
Date Completed	:	23-Apr-09
Purchase Order No.	:	-

Test Article : Clearklens DE 70% 5L
Sample Code : Expiry 03/2011
Batch Reference : ENT 06165 09 091 - 7516049
Laboratory Reference : LR-00845494 **Article Quantity** : 10
Test Required : Sterility Method I: Membrane Filtration by Steritest. BP, Ph Eur and USP.

Test		Method	Result
Sterility Test by Membrane Filtration (Steritest) Method	*	MM107	Pass
Growth in Tryptone Soya Broth at 22°C after 14 days	*	MM107/01	0/1
Growth in Fluid Thioglycollate at 32°C after 14 days	*	MM107/02	0/1
Product Standard Data Sheet	*	MQ002/01	FM03

Day Book Ref: 484010
Volume Tested: 10 x 50mL
Test carried out according to current Pharmacopoeias.

ECP Reçu le
29 MAI 2009
N° 090529 QA

GLP
Compliant Laboratory

Mrs S L Wood, BSc., CBiol., MIBiol
Laboratory Manager - Pharmaceutical Microbiology

Date 27 April 2009

K.A.Barker, C.Biol, M.I. Biol.,
Business Manager - Microbiology

charles river
accelerating drug development. exactly.

RAPPORT D'ESSAI / *ANALYSIS REPORT*
N° 60-077 Révision 1 – Page / *Page* 1 / 1
Annule et remplace le rapport 60-077
Cancel and replace analysis report 60-077

Edité le / *Printed on the* : 29 mai 2009, par / *by* :

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pour le client / *for customer* n° : 7669

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 avril 2009

Date d'analyse
Testing date

08 avril 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 DE 70% 5L

Lot / Prélèvement / Numéro *Batch / Sample / Number*	Concentration en endotoxines *Endotoxin amount*	Unités *Units*
ENT06165 09 091	**<0,25**	**UI/mL**

ECP Reçu le
29 MAI 2009
090529 09A.

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

Opérateur / *Operator*
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Tech. de laboratoire / *Lab. Technician*
29 MAI 2009

Approbateur Qualité / *Quality Reviewer*
N.A.

Approbateur Technique / *Technical Reviewer*
Gilles GOY
Responsable Technique Laboratoire
29 MAI 2009

MedicalLab

Report n° :	09/OI/STE/056
Sponsor :	ECP 385, 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 DE VH29	Order number :	CF090335
Customer reference :	7516049	Internal reference :	-
Batch number :	ENT 08 165 09 091	Material :	-
Date of receipt :	6 avril 2009	Data sterilization :	-
Date of test :	2 juin 2009	Comment(s) :	3/4 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/002

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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