

CONTROL REPORT

Customer JOHNSON Diversey LTD	Management Quality Manual n° MMMQ0000 (contractual)
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Product : ClearKlens DE VH29 70%	Control report n° : CERT 9631B
Specification reference : NA	Purchase order n° : 4700741776
Analyst : LGR	Date of receipt : 14/04/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES	
Customer's batch n° : ENT06301 09 110	ISOTRON certificate n° : 13943401
Date of manufacturing : 14/04/2009	Produced quantity : 167 x 5L
Expiery date : 04/2011	FIDT N° : FIDT 1815 A
ECP's batch n° : 06301	Date of analysis : 14/04/09

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	0,886	0,872 - 0,896
pH (20°C)	NA	9,0	6,0 - 9,0
Microbiological contagion of the EDI	IDT0236	< 1 UFC/100mL	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion : ☒ CONFORM ☐ NOT CONFORM

Date : 30/06/09	Edited: L. GRESSE <i>P10</i>	Checked: D. CHEUNG
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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 : 1L & 5L BOTTLES KITS

Customer's reference : ORDER # CF 090074 OF 26/02/09

Quantity : 5 PALLETS

Irradiation date : 2009.03.01

Irradiation dose : 20.0 kGy to 26.9 kGy

Irradiation batch number : 13943401

Cleanings DE VH29 40%

Lot ENT 06301 09 Mo

Date fab: 14/04/09

Date per: 04/20/11

J. BURGOS & 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 # 13943401 / 1

English translation of the french original certificate.

C. SIMONIN

Quality Officer

Edité le / Printed on the : 20 avril 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

Technique / Method

Méthode D
Colorimétrie cinétique

Sensibilité / Sensitivity

0,005 UI/mL

Date de réception
Simple delivery date

16 avril 2009

Date d'analyse
Testing date

17 avril 2009

Nbre d'échantillons
Number of samples



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

Approbateur Qualité / Quality Reviewer

N.A.

Approbateur Technique / Technical Reviewer

Gilles GOY
Responsable Technique Laboratoire

20 AVR. 2009

endotoxin and microbial detection

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Charles River Laboratories France S.A.S. • Capital: 69 969 360 € • VAT No. FR 29 086 650 041 • SIRET: 086 650 041 00022 • APE: 7219Z

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.

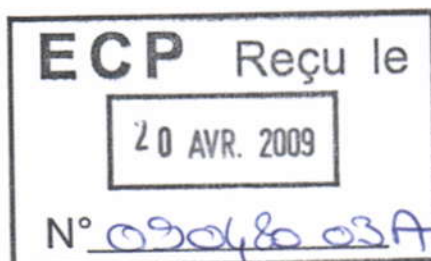
ID produit / product ID
ClearKlens DE 70% 5L

Lot / Prélèvement / Numéro
Batch / Sample / Number

ENT 06301 09 110

Concentration en endotoxines Unités
Endotoxin amount Units

< 0,25 UI/mL



Report n° : **09/OI/STE/059**

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 Pharmacopée Edition

TEST ARTICLE

Name of product :	ClearKlenz DE VH29	Order number :	CF060335
Customer reference :	7515142	Internal reference :	
Batch number :	ENT 06 301 09 110	Material :	
Date of receipt :	16 avril 2009	Data sterilization :	
Date of test :	2 juin 2009	Comment(s) :	3/4 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/005**

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	Approved by :	MARTINHO Alice
	Technicien Biologiste		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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