

**Customer**

DIVERSEY LTD

Management Quality Manual n° MMMQ0000 (contractual)

Product :

Clearklens IPA VH1 70%

Control report n^b :

CERT 11243

Specification reference :

7516050

Analyst :

NMA

Purchase order n^b :

4701070616

Date of receipt :

07/26/2011

PHYSICAL AND CHEMICAL PROPERTIES CONTROL**Customer's batch n^b :** ENT15228 11 208**ISOTRON certificate(s) n^b :** 16730201**Date of manufacturing :** 07/26/2011**Produced quantity :** 160 x 5L**Expiry date :** 07/2013**FIDT N^b :** 1814 ind I**ECP's batch n^b :** 15228**Date of analysis :** 07/26/2011**Résultats :**

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Specific gravity (base) (20°C)	IDT0301	0,871	0,865 - 0,875
Appearance (base) 20°C	NA	C	Clear, colourless liquid
Microbiological contagion of the EDI	IDT0236	8 UFC/ 100 mL	< 10 CFU /100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion :☒

CONFORM

☐

NOT CONFORM

Date : 08/02/2011

Edited : N. MARTZ

Checked : P. PRE

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

ECP Reçu le

14 JUIN 2011

N° 110614 09A

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 : BOTTLE KIT 5L

Customer's reference : ORDER # CF 110497 OF 10/06/11

Quantity : 2 PALLETS

Irradiation date : 2011.06.11

Irradiation dose : 19.3 kGy to 26.7 kGy

Irradiation batch number : 16730201

DIVERSEY LTD

Darkless IPA 70%
Batch ENT15228 M 68

D. GHERSY
20.06.11

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 # 16730201 / 1

C. SIMONIN

Quality Officer



Edité le / Printed on the : 28 juillet 2011, par / by :

pour le client / for customer n° : 7669

Charles River Laboratories

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ECP (Entegris Cleaning Process)

A l'attention Mr Olivier TASSART

A l'attention Mr Damien GHERSY

395 rue Louis Lépine
34000 MONTPELLIER

ECP Reçu le

1 - AOUT 2011

N° 110819 02A

ESSAI DES ENDOTOXINES BACTERIENNES
Bacterial Endotoxins Test

Contrat Technique
Technical Contract

ENDO 90

Technique / Method

Méthode D
Colorimétrie cinétique

Sensibilité / Sensitivity

0,005 UI/mL

Date de réception
Simple delivery date

28 juillet 2011

Date d'analyse
Testing date

28 juillet 2011

Nbre d'échantillons
Number of samples

2

Produit / Product

ClearKlens IPA 70%

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

Lot / Prélèvement / Numéro
Batch / Sample / Number

ENT15227 11 206

ENT15228 11 208

Concentration en endotoxines
Endotoxin amount

Unités
Units

< 0,25 UI/mL

< 0,25 UI/mL

Note : les résultats ne valent que pour le (les) objet(s) soumis à l'essai. Results are valid only for (the) object(s) tested.
D'autre part, le(s) résultat(s) ne tiennent pas compte de l'incertitude de mesure de l'essai. Moreover, result(s) does not take into account the test uncertainty.



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

Approbateur Qualité / Quality Reviewer

Alexia DEVENS
Technicien Management Qualité Spécialisé

Approbateur Technique / Technical Reviewer

Gilles GOY
Responsable Technique Laboratoire

28 JUL. 2011

endotoxin and microbial detection

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CERTIFICATE OF ANALYSIS

Mr. Bill Ashton
Diversy Limited
Cotes Park Industrial Estate
Somercoates
Alfreton
Derbyshire
DE55 4PA

Date Received: 04 Aug 11
Date Tested: 12 Aug 11
Date Completed: 26 Aug 11
Purchase Order: -

Test Article: ClearKlens IPA 70%
Sample Code: 7516050
Batch Ref: ENT 15228 11 208
Qty Received: 10 Containers
Laboratory Reference: 0002119/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

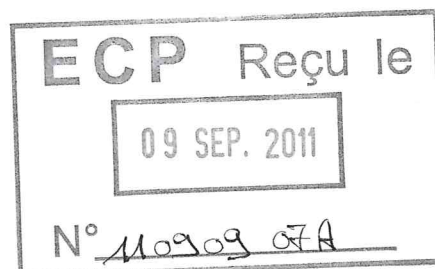
Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Product Standard Data Sheet	FG047/psd	FM03
Volume Tested	MM107/05	10 x 60 mL

External Comments

20 Bottles Sent Testing 10 Bottles Only 10 Spare

External Comments

Test carried out according to current Pharmacopoeias.



Approval is provided by Electronic Signature. Their name is shown below.

Date: 31 Aug 11 12:46:56

Mr K.A. Barker, CBIOL, MSB
Business Manager - Microbiology

Consignment: 0002119
Diversy (Alfreton)

Certificate of Analysis - OSMM

Print Number

P0004853

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