ENTEGRIS CLEANING PROCESS
ECP
An Entegris Company

# CONTROL REPORT

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

| | | | |
|---|---|---|---|
| **Product :** | | **Control report n° :** | CERT 9611 |
| Clearklens Bi-Spore RTU VH26S | | | |
| **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° :** ENT06164 09 090 | **ISOTRON certificate n° :** 13971501 |
| **Date of manufacturing :** 03/2009 | **Produced quantity :** 480 x 5L |
| **Expiery date :** 03/2010 | **FIDT N° :** FIDT 1816 B |
| **ECP's batch n° :** 06164 | **Date of analysis :** 02/04/09 |

**Résultats :**

| Analyzed characteristics | Method of analysis | State in the production | Specification |
|---|---|---|---|
| | | Beginning | |
| Appearance (base) 20°C | NA | C | Clear blue liquid |
| Appearance (base + activator) 20°C | NA | C | Yellow liquid |
| Dosage of the materiel chlorine dioxide | IDT 0261 | 243 ppm | 230 - 280 ppm |
| Specific gravity (base) (20°C) | IDT0301 | 0,999 | 0,990 - 1,010 |
| Specific gravity (base+ activator) (20°C) | | 1,000 | 1,000 - 1,010 |
| pH (base) (20°C) | NA | 2,9 | 2,5 - 4,5 |
| pH (base + activator) (20°C) | | 2,9 | 2,5 - 5,5 |
| 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 : 02/04/09 | Edited: L. GRESSE | Checked: F. GAYRAUD | Approved: C. GARY |
|---|---|---|---|

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mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

# 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 Bi-Spore Base RTU 5L
**Sample Code** : Expiry 03/2010
**Batch Reference** : ENT 06164 09 090 - 7516196
**Laboratory Reference** : LR-00845496 **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 | FM05 |

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

ECP Reçu le
29 MAI 2009
N° 090529 03A

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

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

**Test Article** : Clearklens Bi-Spore Activator RTU 100mL
**Sample Code** : Expiry 03/2010
**Batch Reference** : ENT 06164 09 090 - 7516196
**Laboratory Reference** : LR-00845497 **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 | FM04 |

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

ECP Reçu le
29 MAI 2009
N° 0905 29 03A

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

GLP
Compliant Laboratory

Date 27 April 2009

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

# 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°090529.12A

**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 PRO** |
| **Product** | : | BOTTLES 5L |
| **Customer's reference** | : | ORDER # CF090074 OF 05/03/09 |
| | | Cleanfens Bispore RTU |
| **Quantity** | : | 4 PALLETS Lot ENT 06 164 09 090 |
| | | Date fab : 03/2009 |
| **Irradiation date** | : | 2009.03.07 Date péi : 03/2010 |
| **Irradiation dose** | : | 18.9 kGy to 25.1 kGy |
| **Irradiation batch number** | : | 13971501 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 # 13971501 / 1**
English translation of the french original certificate.

MedicalLab

| | |
|---|---|
| Report n° : | **09/OI/STE/058** |
| Sponsor : | *ECP*<br>395, rue Louis Lépine<br>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 Bi-Spore RTU VH26S | Order number : | CF090335 |
| Customer reference : | 7516196 | Internal reference : | - |
| Batch number : | ENT 06 164 09 090 | Material : | - |
| Date of receipt : | 6 avril 2009 | Data sterilization : | - |
| Date of test : | 2 juin 2009 | Comment(s) : | Fin de production<br>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/004**

## 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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29 JUIN 2009
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