



#### Contact

JohnsonDiversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands Tel. +31 (0)30 247 6427

### **CERTIFICATE OF ANALYSIS**

Date: 3.11.10

| Product Name    | CLEARKLENS IPA VH1 |            |  |
|-----------------|--------------------|------------|--|
| Product Code    | 7513400            |            |  |
| Batch Number    | NO 28912           |            |  |
| Production Date | 2010111            |            |  |
| Expiry Date     | 2012/11            | Beat Ellis |  |

This is to certify that the above batch of product has been tested internally and conforms to the manufacturing Quality Control specification for the product.

| Test                    | Test Method | Limits           | Results         |
|-------------------------|-------------|------------------|-----------------|
| Appearance              | Visual      | Clear Colourless | Clean Cowuntess |
|                         |             | Liquid           | Liqueid         |
| Specific Gravity (20°C) | JDM004      | 0.872 - 0.883    | 0.843           |

"SIGNATURE" C Pascae

Name Carolina Pascae

Function Name Pharmaroom Supavisor

Please note Johnsondiversey did change the company name to Diversey and is in the phase of implementation

CoA 7513400 v2.doc 17th August 2010 W Ashton

# CERTIFICATE OF IRRADIATION Number: B

0469399 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd

P016164 18/11/10



Page 1

### **Isotron Limited**

Roydsdale Way · Euroway Trading Estate

Bradford · West Yorkshire BD4 6SE · United Kingdom Telephone: +44 (0)1274 686011 Facsimile: +44 (0)1274 686061 Email: assistance@isotron.com

Website: www.isotron.com

| Date: 29/11/               | ′10                     |      |   |
|----------------------------|-------------------------|------|---|
| ITEM CODE<br>ISOTRON BATCH | ITEM SPECIFICATION      | QTY  | ADDITIONAL DETAILS  |
| B2FLE0010081<br>B210110726 | JD IPA BOTTLES 25-45kGy | 696  | B/No.W028912<br>ACTUAL DOSE37.0 - 38.5kGy                       |
| B2FLE0010999<br>B210110726 | SAMPLES                 | 5    |   |
|                            |                         |      | CUSTOMERS BATCH/CODE No.s AS ORDER<br>No.P016164 DATED 17/11/10 |
|                            |                         |      |   |
|                            |                         |      |   |
|                            |                         |      |   |
|                            |                         |      |   |
|                            | Despatch Text:          |      |   |
|                            | 13PLTS                  |      |   |
|                            | Total                   | 701. | Last Page 1 of 1  |

All in accordance with current technical agreement

This is to certify that the above items have been irradiated as specified above

Authorising Signature:

For and on behalf of ISOTRON LIMITED



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire P017 5EU England Telephone: +44(0)1329 832511

Fax:

Date Received:

Date Completed:

Purchase Order:

Date Tested:

+44(0)1329 834262

06 Dec 10

07 Dec 10

07 Dec 10

16245

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

# CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8

Hightown

White Cross Industrial Estate

Lancaster LA14XS

Test Article:

ClearKlens IPA Block 1

Sample Code:

Work Order No. 28912

Batch Ref:

2203

Oty Received:

1 x 900mL

Laboratory Reference:

0000783/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

| Method Item | Result                                       |  |  |
|-------------|--|--|--|
| MM110/00    | <0.2 EU/mL                                   |  |  |
| MM110/01    | 79 %   |  |  |
| MM110/02    | 0.5 EU/mL                                    |  |  |
| MM110/04    | 1/40   |  |  |
| MM110/05    | FM02   |  |  |
|             | MM110/00<br>MM110/01<br>MM110/02<br>MM110/04 |  |  |

### **External Comments**

Test carried out according to current Pharmacopoeias.

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

Eliza Llacat

Date:

08 Dec 10 17:01:43

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0000783

Certificate of Analysis - OSMM

Print Number

P0002026

Lancaster

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Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire P017 5EU England Telephone: +44(0)1329 832511

Fax:

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06 Dec 10

15 Dec 10

29 Dec 10

16245

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

## CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8

Hightown

White Cross Industrial Estate

Lancaster LA14XS

Test Article:

ClearKlens IPA Block 1

Sample Code:

Work Order No. 28912

Batch Ref:

2203

Qty Received:

20 x 900mL

Laboratory Reference:

0000783/1

Test Required:

Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

| Test   | Method Item | Result                 |
|--|-------------|------------------------|
| Sterility Test by Membrane Filtration (Steritest)<br>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                                    | MM107/03    | FM03                   |
| Day Book Reference   | MM107/04    | 000066                 |
| Volume Tested  | MM107/05    | 20 x 50 mL             |

### **External Comments**

Test carried out according to current Pharmacopoeias.

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

Shire Llead.

Date:

05 Jan 11 11:06:17

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment:

0000783

Certificate of Analysis - OSMM

Print Number

P0002332

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