

# CERTIFICATE OF ANALYSIS

| PRODUCT NAME    | CLEARKLENS IPA VH01 7513400 |  |  |
|-----------------|-----------------------------|--|--|
| PRODUCT CODE    |                             |  |  |
| BATCH NUMBER    | W027859                     |  |  |
| PRODUCTION DATE | 05-2010                     |  |  |
| EXPIRY DATE     | 05-2012                     |  |  |

| TEST           | TEST METHOD LIMITS |                            | RESULTS       |  |
|----------------|--------------------|----------------------------|---------------|--|
| Appearance     | VISUAL.            | Clear Colourless<br>Liquid | CLEAR LIQUID. |  |
| Density (20°C) | GM 0110 01         | 0.865 - 0.885              | 0.810.        |  |

| Date: 24 05 2010 |
|------------------|
| QA.Manager:      |
| QA.Manager:      |
| QA: E Garagne    |
| JD Approval:     |

This document has been produced on behalf of JohnsonDiversey by authorised personnel and is valid unsigned.

Issue no. 4
Issued by W. Ashton
Issue date 07,04,2006

## CERTIFICATE OF IRRADIATION Number: B

0447406 00

FLEOO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd

P015419 13/05/10



Fage 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: 18/05/               | , Tri                   |     |  |
|----------------------------|-------------------------|-----|--|
| ITEM CODE<br>ISOTRON BATCH | ITEM SPECIFICATION      | QTY | ADDITIONAL DETAILS   |
| B2FLE0010081<br>B210050328 | JD IPA BOTTLES 25-45kGy | 353 | BATCH NO: W027859-CUSTB/NO: 1699                               |
|                            |                         |     | ACTUAL DOSE37.4 - 38.2kGy                                      |
| B2FLE0010999<br>B210050328 | SAMPLES                 | 5   | CUSTOMER BATCH/CODE NO'S ON ORDER NO<br>P015419 DATED 12.05.10 |
|                            |                         |     |  |
|                            |                         |     |  |
|                            |                         |     |  |
|                            |                         |     |  |
|                            |                         |     |  |
|                            |                         |     |  |
|                            |                         |     |  |
|                            | Despatch Text:          |     |  |
|                            | 7PLTS                   |     |  |
|                            |                         |     |  |
|                            | Total                   | 358 | 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 PO17 5EU England Telephone: +44(0)1329 832511

+44(0)1329 834262

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 LA1 4XS

Date Received

24-May-10

**Date Tested** 

02-Jun-10

**Date Completed** 

02-Jun-10

Purchase Order No.

15461

Test Article

: ClearKlens IPA Block 1

Sample Code

**Batch Reference** 

: 1699 W027859

Laboratory Reference

: LR-00964487

Article Quantity : 1 x 900mLs

Test Required

: LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. Ph Eur and USP.

| Test   |   | Method   | Result        |
|--|---|----------|---------------|
| Bacterial Endotoxin by LAL, Kinetic QCL Test | * | MM110    | <0.2000 EU/mL |
| Dilution                                     | * | MM110/01 | 1/40          |
| Spiked Recoveries                            | * | MM110/02 | Valid 71%     |
| Endotoxin Spike Level                        | * | MM110/09 | 0.5 EU/mL     |
| Product Standard Data Sheet                  | * | MQ002/01 | FM02          |

Test carried out according to current Pharmacopoeias.

Date 10 /10 2010

Compliant Laboratory

GLP

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00150854

Certificate of Analysis - OSMM

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

+44(0)1329 834262

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 LA1 4XS

**Date Received** 24-May-10

**Date Tested** 02-Jun-10 :

**Date Completed** 16-Jun-10

Purchase Order No. 15461 :

**Test Article** 

: ClearKlens IPA Block 1

Sample Code

**Batch Reference** 

: 1699 WO27859

Laboratory Reference

: LR-00964486

Article Quantity : 20 x 900mLs

Test Required

: Sterility Method I: Membrane Filtration by Steritest. Ph Eur and USP.

| Test  |   | Method   | Result |
|---|---|----------|--------|
| Sterility Test by Membrane Filtration (Steritest)<br>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: 900002 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00150854

Certificate of Analysis - OSMM

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GLP Compliant Laboratory