

**CERTIFICATE OF IRRADIATION**    Number: **B**    0381278 00

FLE001

Page 1

Flexible Medical Packaging Ltd  
 Unit 8  
 White Cross Industrial Estate  
 Hightown  
 Lancaster



**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

LA1 4XS

Cust. Ref: PO13083  
 Date Rec'd 28/08/08  
 Date: 2/09/08

| ITEM CODE<br>ISOTRON BATCH | ITEM SPECIFICATION      | QTY | ADDITIONAL DETAILS   |
|----------------------------|-------------------------|-----|--|
| B2FLE0010081<br>B208090005 | JD IPA BOTTLES 25-45kGy | 165 | E/No.W024954<br><br>ACTUAL....26.3 - 37.8....kGy<br>DOSE   |
| B2FLE0010999<br>B208090005 | SAMPLES                 | 4   | <br><br><br><br><br><br><br><br><br><br>CUSTOMERS BATCH/CODE No.s AS ORDER<br>No.PO13083 DATED 27/8/08 |
|                            | Total                   | 169 | 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: *C Drace*

For and on behalf of ISOTRON LIMITED



**CERTIFICATE OF ANALYSIS**

Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8, Hightown  
White Cross Industrial Estate  
Lancaster LA1 4XS

**Date Received** : 10-Sep-08  
**Date Tested** : 12-Sep-08  
**Date Completed** : 12-Sep-08  
**Purchase Order No.** : P013130

**Test Article** : Clearlens IPA  
**Sample Code** :  
**Batch Reference** : WO24954  
**Laboratory Reference** : LR-00788060 **Article Quantity** : 1 x 900mL  
**Test Required** : LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. BP, Ph Eur and USP.

| Test   | Method     | Result     |
|--|------------|------------|
| Bacterial Endotoxin by LAL, Kinetic QCL Test | * MM110    | <0.2 EU/mL |
| Dilution                                     | * MM110/01 | 1/40       |
| Spiked Recoveries                            | * MM110/02 | 75 Valid   |
| Endotoxin Spike Level                        | * MM110/09 | 0.5 EU/mL  |

This sample was tested at a 1/40 dilution and spiked with endotoxin to check for interference.  
Test carried out according to current Pharmacopoeias.  
Product Standard Data Sheet: FM02

*Suz Wood*

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

Date 17 Sep 2008



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



**CERTIFICATE OF ANALYSIS**

Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8, Hightown  
White Cross Industrial Estate  
Lancaster LA1 4XS

**Date Received** : 10-Sep-08  
**Date Tested** : 18-Sep-08  
**Date Completed** : 02-Oct-08  
**Purchase Order No.** : P013130

**Test Article** : Clearklens IPA  
**Sample Code** :  
**Batch Reference** : WO24954  
**Laboratory Reference** : LR-00788059 **Article Quantity** : 20 x 900mL  
**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 | FM03   |

Day Book Ref: 226045  
Volume Tested: 20 x 50mL  
Test carried out according to current Pharmacopoeias.



*WKB*

Date 7 Oct 2008

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



CERTIFICATE OF ANALYSIS

|                 |                     |
|-----------------|---------------------|
| PRODUCT NAME    | CLEARKLENS IPA VH01 |
| PRODUCT CODE    | 7513400             |
| BATCH NUMBER    | W024954             |
| PRODUCTION DATE | 08/2008             |
| EXPIRY DATE     | 08/2010             |

| TEST           | METHOD     | LIMITS                  | RESULTS                 |
|----------------|------------|-------------------------|-------------------------|
| Appearance     |            | Clear Colourless Liquid | Clear colourless liquid |
| Density (20°C) | GM 0110 01 | 0.865 - 0.885           | 0.876                   |

Date: 08/09/08

QA Manager: [Signature]

QA: [Signature]

JD Approval: [Signature] 8/9/08

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

Issue no. 4  
Issued by W. Ashford  
Issue date 07.04.2006