

FLE001

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



**Isotron Limited**

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 Facsimile: +44 (0)1274 686061  
 Email: assistance@isotron.com  
 Website: www.isotron.com

LA1 4XS

Cust. Ref: P013201  
 Date Rec'd 1/10/08  
 Date: 8/10/08

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B208100109	JD IPA BOTTLES 25-45kGy	486	B/No.W024967  ACTUAL...39.4 - 40.2...kGy DOSE
B2FLE0010999 B208100109	SAMPLES	4	
Total		490	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: *[Signature]*

For and on behalf of ISOTRON LIMITED



**CERTIFICATE OF ANALYSIS**

PRODUCT NAME	CLEARKLENS IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W024967
PRODUCTION DATE	09 / 2008
EXPIRY DATE	10 / 2010

TEST	METHOD	LIMITS	RESULTS
Appearance		Clear Colourless Liquid	clear colourless liquid.
Density (20°C)	GM 0110 01	0.865 – 0.885	0.875

Date:.....10/10/08.....

QA Manager:.....*[Signature]*.....

QA:.....*[Signature]*.....

JD Approval:.....*[Signature]*.....

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



**CERTIFICATE OF ANALYSIS**

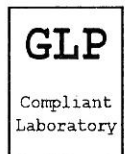
Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8, Hightown  
White Cross Industrial Estate  
Lancaster LA1 4XS

**Date Received** : 17-Oct-08  
**Date Tested** : 23-Oct-08  
**Date Completed** : 23-Oct-08  
**Purchase Order No.** : PO13259

**Test Article** : Clearklens IPA  
**Sample Code** : Works Order No. 24967  
**Batch Reference** : 74  
**Laboratory Reference** : LR-00797378 **Article Quantity** : 1  
**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	<0.2000 EU/mL
Dilution	*	MM110/01	1/40
Spiked Recoveries	*	MM110/02	76% 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:



*WKB*

Date 30 Oct 2008

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

**Sample Booking Number:** CN\00127459  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

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## CERTIFICATE OF ANALYSIS

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

**Date Received** : 17-Oct-08  
**Date Tested** : 21-Oct-08  
**Date Completed** : 04-Nov-08  
**Purchase Order No.** : PO13259

**Test Article** : Clearklens IPA  
**Sample Code** : Works Order No. 24967  
**Batch Reference** : 74 W024967  
**Laboratory Reference** : LR-00797377 **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: 306008  
Volume Tested: 20x50mL  
Test carried out according to current Pharmacopoeias.

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

Date 06 Nov 2008



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

**Sample Booking Number:** CN00127459  
Flexible Medical Packaging Limited

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