



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W026852
PRODUCTION DATE	09/2009
EXPIRY DATE	09/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.865 - 0.885	0.877

Date: 02/10/09

QA Manager: [Signature]

QA: [Signature]

JD Approval: [Signature]

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

FLE001

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



**Isotron Limited**

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 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: P014583  
 Date Rec'd 23/09/09  
 Date: 28/09/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209090540	JD IPA BOTTLES 25-45kGy	528	B/No.W026852  ACTUAL...35.2 - 38.4...kGy DOSE
B2FLE0010999 B209090540	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.P014583 DATED 22/9/09
Total		530	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: *J. Coffey*

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** : 08-Oct-09  
**Date Tested** : 12-Oct-09  
**Date Completed** : 12-Oct-09  
**Purchase Order No.** : PO14651

**Test Article** : Clearlens IPA Block 1  
**Sample Code** :  
**Batch Reference** : WO26852  
**Laboratory Reference** : LR-00895001 **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	<0.2000 EU/mL
Dilution	* MM110/01	1/40
Spiked Recoveries	* MM110/02	Valid
Endotoxin Spike Level	* MM110/09	0.5 EU/mL
Product Standard Data Sheet	* MQ002/01	FM02

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

*WAB*

Date 20 Oct 2009



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

**Sample Booking Number:** CN\00141614  
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** : 08-Oct-09  
**Date Tested** : 21-Oct-09  
**Date Completed** : 04-Nov-09  
**Purchase Order No.** : PO14651

**Test Article** : Clearklens IPA Block 1  
**Sample Code** :  
**Batch Reference** : WO26852  
**Laboratory Reference** : LR-00895002 **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: 649026  
Volume Tested: 20 x 50mL  
Test carried out according to current Pharmacopoeias.

*Suz Wood*

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

Date 06 Nov 2009



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

**Sample Booking Number:** CN00141614  
Flexible Medical Packaging Limited

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