



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARLENs IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W025311
PRODUCTION DATE	12/2008
EXPIRY DATE	12/2010

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

Date:.....22/12/08.....

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

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

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

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

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: P013493  
 Date Rec'd 8/12/08  
 Date: 16/12/08

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B208120404	JD IPA BOTTLES 25-45kGy	688	B/No.W025311  ACTUAL <u>35.7 - 39.5</u> kGy DOSE
B2FLE0010999 B208120404	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.P013493 DATED 8/12/08    16/12/08
Total		690	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



**CERTIFICATE OF ANALYSIS**

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

**Date Received** : 08-Apr-09  
**Date Tested** : 15-Apr-09  
**Date Completed** : 15-Apr-09  
**Purchase Order No.** : PO13557

**Test Article** : Clearklens IPA  
**Sample Code** :  
**Batch Reference** : W025311  
**Laboratory Reference** : LR-00845622 **Article Quantity** : 20x900mls  
**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.

*Signature*

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

Date 27 April 2009



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

**Sample Booking Number:** CN\00134188  
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-Apr-09  
**Date Tested** : 15-Apr-09  
**Date Completed** : 29-Apr-09  
**Purchase Order No.** : PO13557

**Test Article** : Clearklens IPA

**Sample Code** :

**Batch Reference** : W025311

**Laboratory Reference** : LR-00845621

**Article Quantity** : 23x900mls


**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: 484010

Volume Tested: 20x50mL

Test carried out according to current Pharmacopoeias.

  
Mrs S L Wood, MSc, CEng, MIBiol  
Laboratory Manager - Pharmaceutical Microbiology



Date 30 April 2009

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

**Sample Booking Number:** CN\00134188  
Flexible Medical Packaging Limited

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