



## CERTIFICATE OF ANALYSIS

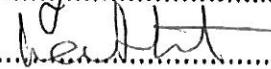
PRODUCT NAME	CLEARLENs IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W026272
PRODUCTION DATE	06/2009
EXPIRY DATE	06/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.865 – 0.885	0.873

Date:.....26/10/09.....

QA Manager:..........

QA:.....E. Garagm.....

JD Approval:..........

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

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: P014168  
Date Rec'd 11/06/09  
Date: 22/06/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209060510	JD IPA BOTTLES 25-45kGy	48	B/No.W026272 - CUSTOMER B/No.599  ACTUAL.....37.0 - 37.1.....kGy DOSE
B2FLE0010999 B209060510	SAMPLES	2	    CUSTOMERS BATCH/CODE No.s AS ORDER No.P014168 DATED 10/6/09
B2FLE001VAL	VALIDATION		SINGLE VALIDATION
Total		50	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

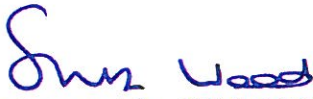
Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8, Hightown  
White Cross Industrial Estate  
Lancaster LA1 4XS

**Date Received** : 25-Jun-09  
**Date Tested** : 29-Jun-09  
**Date Completed** : 29-Jun-09  
**Purchase Order No.** : PO14212

**Test Article** : Clearklens IPA Block 1  
**Sample Code** : Works Order No. 26272  
**Batch Reference** : 599  
**Laboratory Reference** : LR-00866916 **Article Quantity** : 1 Bottle  
**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	92% 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.

  
Mrs S L Wood, B.Sc., C.Biol., M.Biol.  
Laboratory Manager - Pharmaceutical Microbiology

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

Date 08 July 2009

**GLP**  
Compliant  
Laboratory

**Sample Booking Number:** CN00137342  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

Page 1 of 1

*This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited*



## CERTIFICATE OF ANALYSIS

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

Date Received : 25-Jun-09  
Date Tested : 26-Jun-09  
Date Completed : 10-Jul-09  
Purchase Order No. : PO14212

Test Article : Clearklens IPA Block 1  
Sample Code : Works Order No. 26272  
Batch Reference : 599  
Laboratory Reference : LR-00866915 Article Quantity : 20 Bottles  
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: 574013

Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

*Signature*  
K.A. Barker, C.Biol., M.I. Biol.  
Laboratory Manager - Pharmaceutical Microbiology

Date

15 July 2009

GLP

Compliant  
Laboratory

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

Sample Booking Number: CN\00137342  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

Page 1 of 1

*This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited*