

## CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01		
PRODUCT CODE	7514372		
BATCH NUMBER	WO26153.		
PRODUCTION DATE	06/2009		
EXPIRY DATE	06/2011		

TEST	METHOD	LIMITS	RESULTS	
Appearance	VISUAL	Clear Colourless Liquid	CLEAR COlouris	
Density (20°C)	GM 0110 01	0.865 - 0.885	0.875,	

QA.Manager:	Date: 26/06/05/
QA: E: Garage	Date: 26-06-00)
QA: E. Gaunge	Date: 23/06/2009
Date above relates to the date of signing of the person.	· ·

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

Issue no. 6 Issued by W. Ashton Issue date 26,06,2009

# CERTIFICATE OF IRRADIATION Number: B

0411867 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: P014198
Date Rec'd 18/06/09



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#### **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

Date: 25/06/	/09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209060538	JD IPA BOTTLES 25-45kGy	656	B/No.W026153 - CUSTOMER B/No.599 P/REF.7514372 - LABELLED UN1219
			ACTUAL38.9 - 40.4kGy DOSE
B2FLE0010999 B209060538	SAMPLES	2	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P014198 DATED 17/6/09
4 Boxes	s collected by Sally Water	en 25/c	Selog 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



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire P017 5EU England Telephone: +44(0)1329 832511

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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 : 26-Jun-09

Date Tested : 02-Jul-09

Date Completed : 02-Jul-09

Purchase Order No. : PO14217

**Test Article** 

: Clearklens IPA Block 2

Sample Code

: Works Order No. 26153

**Batch Reference** 

: 599

Laboratory Reference

: LR-00867669

Article Quantity : I 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	77 % 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, BSc., CBiol., MIBiol
La hotalory Manager - Pharmaceutical Microbiology

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

CN\00137464

Certificate of Analysis - OSMM

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GLP

Compliant Laboratory

Sample Booking Number: Flexible Medical Packaging Limited

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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

26-Jun-09

**Date Tested** 

30-Jun-09

**Date Completed** 

14-Jul-09

Purchase Order No.

PO14217

**Test Article** 

: Clearklens IPA Block 2

Sample Code

: Works Order No. 26153

**Batch Reference** 

: 599

Laboratory Reference

: LR-00867668

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: 574015 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

Mrs S L Wood ESc. CBio', MBiol Laboratory Manager Fnannaceutical Microbiology

Compliant Laboratory

GLP

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

Sample Booking Number:

CN\00137464

Certificate of Analysis - OSMM

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