

## **CERTIFICATE OF ANALYSIS**

PRODUCT NAME	CLEARKLENS IPA VH01		
PRODUCT CODE	7514372		
BATCH NUMBER	WO 26340		
PRODUCTION DATE	10/2009		
EXPIRY DATE	10/2011		

TEST	METHOD	LIMITS	RESULTS
Appearance	VISual	Crear Coroaness	Clear colourless
		Liquid	22/2014
Density (20°C)	GM 0110 01	0.865 - 0.885	0.877

QA.Manager:	Date: 221 101091
QA: E Crausia	Date: 22-10 09
JD Approval:	Date: 22/10/09
Date above relates to the date of signing of the person.	* *

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

# CERTIFICATE OF IRRADIATION Number: B

isotron

0423790 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref:

P014655 8/10/09

Date Rec'd



### **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

Date: 12/10/			
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209100222	JD IPA BOTTLES 25-45kGy	532	B/No.W026840 - PRODUCT REF.7514372
			ACTUAL38.739.9kGy DOSE
B2FLE0010999 B209100222	SAMPLES	2	ye.
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P014655 DATED 7/10/09
,			
	Total	534	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

+44(0)1329 834262

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

#### CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

**Date Received** 

20-Oct-09

**Date Tested** 

27-Oct-09

**Date Completed** 

27-Oct-09

Purchase Order No.

14698

**Test Article** 

: Clearklens IPA Block 2

Sample Code

: WO26840

**Batch Reference** 

: 1277

Laboratory Reference

: LR-00898632

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	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.

Mr K A Barker, CBiol., MSB **Business Manager** 

Date 29 Och 2009

Compliant Laboratory

GLP

Mrs S.L. Wood, B.Sc. (Hons), C.Biol., MSB.,

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00142118

Certificate of Analysis - OSMM

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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** 

20-Oct-09

**Date Tested** 

28-Oct-09

**Date Completed** 

11-Nov-09

Purchase Order No.

14698

**Test Article** 

: Clearklens IPA Block 2

Sample Code

: WO26840

**Batch Reference** 

: 1277

Laboratory Reference

: LR-00898631

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: 649033 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

Phuong Phan-Lengoe, use (Hons), CBiol, MSB

Deputy Laboratory Manager - Microbiology

Date 19 NOV 2009

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

Sample Booking Number: Flexible Medical Packaging Limited

CN\00142118

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