

### CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01		
PRODUCT CODE	7513400		
BATCH NUMBER	W025337		
PRODUCTION DATE	03/2009		
EXPIRY DATE	03/2011		

TEST METHOD		LIMITS	RESULTS	
Appearance	visual	Clear Colourless Liquid	clear colociless unquid	
Density (20°C)	GM 0110 01	0.865 - 0.885	0.877	

Date: 27/03/09
QA.Manager: LOCO
QA: £ Gauge
D Approval: La ALL

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

Issue no. 4 Issued by W. Ashton Issue date 07.04.2006

# CERTIFICATE OF IRRADIATION Number: B

0400857 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd P013790 5/03/09

12/03/09



Page

#### **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: 12/03/	<b>'</b> 09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209030240	JD IPA BOTTLES 25-45kGy	528	B/No.W025337
B257555215			ACTUAL39.8 - 41.9kGy DOSE
B2FLE0010999 B209030240	SAMPLES	2	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013790 DATED 4/3/09
4			
	Total	530	Last Page 1 of 1
		All in acco	rdance with current

All in accordance with current technical agreement

This is to certify that the above items have been irradiated as specified above

Authorising Signature: 

Drace

For and on behalf of ISOTRON LIMITED



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#### **CERTIFICATE OF ANALYSIS**

Mr J Jackson

Date Received : 18-Mar-09

Flexible Medical Packaging Limited

: 27-Mar-09

Unit 8, Hightown

Date Completed : 27-Mar-09

White Cross Industrial Estate

Purchase Order No. : 13838

Lancaster LA1 4XS

**Test Article** 

: Clearklens IPA Block 1

Sample Code

:

**Batch Reference** 

: WO25337

Laboratory Reference

: LR-00839545

Article Quantity: 1

**Date Tested** 

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.

**GLP**Compliant

Laboratory

K.A.Barker, C.Biol, M.I. Biol.,

Business Manager - Microbiology

Sample Booking Number: CN\00133351

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

18-Mar-09 **Date Received** :

20-Mar-09 **Date Tested** :

03-Apr-09 **Date Completed** 

13838 Purchase Order No.

**Test Article** 

: Clearklens IPA Block 1

Sample Code

**Batch Reference** 

: WO25337

Laboratory Reference

: LR-00839546

Article Quantity : 22

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: 380041 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Date Of Apr los

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

Sample Booking Number:

CN\00133351

Certificate of Analysis - OSMM

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