

## CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01		
PRODUCT CODE	7513400		
BATCH NUMBER	W014957		
PRODUCTION DATE	09/2008		
EXPIRY DATE	09/2010		

TEST METHO		LIMITS	RESULTS	
Appearance		Clear Colourless Liquid	Clear colourless	
Density (20°C)	GM 0110 01	0.865 - 0.885	0.877	

Date:	10/	10/08	·	•••••••	*******
QA.Man	ager:/	Jehen j	kolizazi.	.,	
QA.:	$\mathcal{E}G_{\mathfrak{a}}$	notm.			
JD Appro	oval:	.he	ARA	~~~	

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

0382851 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref:

P013143 11/09/08

Date Rec'd Date:

15/09/08



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

ITEM CODE . ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B208090319	JD IPA BOTTLES 25-45kGy	171	B/No.W024957
5200070317			ACTUAL36.0 - 38.4kGy DOSE
B2FLE0010999 B208090319	SAMPLES	4	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013143 DATED 10/9/08
	*		
			ē
	Total	175	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: 

Droce

For and on behalf of ISOTRON 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** 23-Sep-08

**Date Tested** 25-Sep-08

09-Oct-08 **Date Completed** 

PO13175 Purchase Order No.

**Test Article** 

: ClearKlens IPA

Sample Code

**Batch Reference** 

: WO24957

Laboratory Reference

: LR-00791345

Article Quantity : 20 x 900mL

**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: 226052 Volume Tested: 1 Litre

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Date 4 Och 2008

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

Sample Booking Number:

CN\00126546

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** 

23-Sep-08

**Date Tested** 

01-Oct-08

**Date Completed** 

01-Oct-08

Purchase Order No.

PO13175

**Test Article** 

: ClearKlens IPA

Sample Code

**Batch Reference** 

: WO24957

**Laboratory Reference** 

: LR-00791346

Article Quantity : 20 x 900mL

**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	<0.2 EU/mL
Dilution	*	MM110/01	1/40
Spiked Recoveries	*	MM110/02	94% Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL

This sample was tested at a 1/40 dilution and spiked with endotoxin to check for interference.

Test carried out according to current Pharmacopoeias.

Product Standard Data Sheet: FM02

GLP

Compliant Laboratory

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

Sample Booking Number:

Business Manager - Microbiology

CN\00126546

Certificate of Analysis - OSMM

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Date tock 2008