

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01		
PRODUCT CODE	7513400		
BATCH NUMBER	WO 75197		
PRODUCTION DATE	01/2009		
EXPIRY DATE	01/2011		

TEST	METHOD	LIMITS	RESULTS	
Appearance	Visoal	Clear Colourless Liquid	clear coportess	
Density (20°C)	GM 0110 01	0.865 - 0.885	0.885	

Date:	102	los.		 ********
QA.Manager:				
QA.:£(laspey.V	·····	******	 *********
JD Approval:		Edw	41	 Manager School Service

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

0396253 00

FLEG01

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd

P013630 22/01/09



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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: 27/01.	/09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209010499	JD IPA BOTTLES 25-45kGy	497	B/No.W025192
			ACTUAL40.3 - 42.0kGy DOSE
B2FLE0010999 B209010499	SAMPLES	2	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013630 DATED 21/1/09
	Total	499	Last Page 1 of 1
		A 400-100-100-100-100-100-100-100-100-100-	

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 Rôad, Wickham, Fareham, Hampshire PO17 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

06-Feb-09

Date Tested

12-Feb-09

Date Completed

12-Feb-09

Purchase Order No.

13693

Test Article

: ClearKlens IPA Block 1

Sample Code

: Batch No: 428

Batch Reference

: WO25192

Laboratory Reference

: LR-00827677

Article Quantity: 1

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	107% Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM02

This sample was tested at a 1/50 dilution and spiked with endotoxin to check for interference. Test carried out according to current Pharmacopoeias.

MAG

Date 19 Feb Lies

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

Sample Booking Number:

Flexible Medical Packaging Limited

CN\00131766

Certificate of Analysis - OSMM

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GLP

Compliant Laboratory

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:

CERTIFICATE OF ANALYSIS (INTERNAL USE ONLY)

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received

06-Feb-09

Date Tested

17-Feb-09

Date Completed

03-Mar-09

Purchase Order No.

13693

Test Article

: ClearKlens IPA Block 1

Sample Code

: Batch No: 428

Batch Reference

: WO25192

Laboratory Reference

: LR-00827676

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: 380023 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Date 05 Mar 2009

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

Sample Booking Number:

CN\00131766

Certificate of Analysis - OSMM

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