

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01		
PRODUCT CODE	7513400		
BATCH NUMBER	W025765		
PRODUCTION DATE	03/2009		
EXPIRY DATE	03/2011		

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

Date:2	7/05/0	9	
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	Jana m		
JD Approval	he	ALX	7

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

mber: **B** 0401653 00

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FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd P013813

12/03/09 19/03/09



Isotron Limited

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

Authorising Signature:

For and on behalf of ISOTRON LIMITED

specified above

Page

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BD4 6SE · United Kingdom
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Facsimile: +44 (0)1274 686061
Email: assistance@isotron.com
Website: www.isotron.com

Date Rec'd 12/03/09 Date: 19/03/09		i .		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS	
B2FLE0010081 B209030405	JD IPA BOTTLES 25-45kGy	173	B/No.25765 ACTUAL38.5 - 40.2kGy DOSE	
B2FLE0010999 B209030405	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.PO13813 DATED 11/3/09	
	Total	175	Last Page 1 of 1	
		All in acco technical a	ordance with current agreement	



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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 30-Mar-09

Date Tested : 31-Mar-09

Date Completed 31-Mar-09

Purchase Order No. 13881

Test Article

: Clearklens IPA Block 1

Sample Code

: Works Order: 25765

Batch Reference

: 581

Laboratory Reference

: LR-00842473

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	82% 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\00133768

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 30-Mar-09

Date Tested 01-Apr-09 :

Date Completed 15-Apr-09

Purchase Order No. 13881

Test Article

: Clearklens IPA Block 1

Sample Code

: Works Order: 25765

Batch Reference

: 581

Laboratory Reference

: LR-00842472

Article Quantity : 20Bottlesx900mL

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: 484004 Volume Tested: 1Ltr

Test carried out according to current Pharmacopoeias.

Laboratory Manager - Fnarmaceutical Microbiology

Compliant Laboratory

GLP

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

GCP GMP GLP PO

Sample Booking Number:

CN\00133768

Certificate of Analysis - OSMM

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