

## CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W025335
PRODUCTION DATE	02/2009
EXPIRY DATE	02/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless Ciquid
Density (20°C)	GM 0110 01	0.865 - 0.885	0.875

Date: 17/02/05	]
QA.Manager:Q	
QA: K. Clausegh	· ·
JD Approval:	Atha

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

0397771 00

FLECO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd P013692 5/02/09 isotron

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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 Rec'd 9/02/			
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209020197	JD IPA BOTTLES 25-45kGy	175	B/No.W025335
			ACTUAL39.1 - 40.2kGy DOSE
B2FLE0010999 B209020197	SAMPLES	2	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013692 DATED 5/2/09
	Total	177	Last Page 1 of 1
		A11	

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 PO17 5EU England Telephone: +44(0)1329 832511

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

Fax:

### CERTIFICATE OF ANALYSIS

Mr J Jackson Date Received 18-Feb-09 Flexible Medical Packaging Limited Date Tested 24-Feb-09 : Unit 8, Hightown **Date Completed** 10-Mar-09 White Cross Industrial Estate Lancaster LA1 4XS Purchase Order No. PO 13739

**Test Article** 

: Clearklens IPA Block 1

Sample Code

**Batch Reference** 

: W025335

Laboratory Reference

: LR-00832064

Article Quantity : 23 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: 380029 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Date 16 Mw los

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

Sample Booking Number:

CN\00132317

Certificate of Analysis - OSMM

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#### CERTIFICATE OF ANALYSIS

Mr J Jackson Date Received 18-Feb-09 Flexible Medical Packaging Limited **Date Tested** 04-Mar-09 Unit 8, Hightown **Date Completed** 04-Mar-09 White Cross Industrial Estate Purchase Order No. PO 13739 Lancaster LA1 4XS

**Test Article** 

: Clearklens IPA Block 1

Sample Code

**Batch Reference** 

: W025335

Laboratory Reference

: LR-00832065

Article Quantity : 1 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	<0.2000 EU/mL
Dilution	*	MM110/01	1/40
Spiked Recoveries	*	MM110/02	98% 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

Date 12 Mar 2001

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

Sample Booking Number:

CN\00132317

Certificate of Analysis - OSMM

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