

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE		
PRODUCT CODE	6069643		
BATCH NUMBER	ю0 26853		
PRODUCTION DATE	2009 /09		
EXPIRY DATE	2011 /09		

TEST	METHOD	LIMITS	RESULTS
Appearance	Vinual	Clear Colourless Liquid	clear Colourless
Density (20°C)	GM 0110 01	0.876 - 0.896	0. 882

Date:i??duchccc	
QA.Manager:	\bigcirc
QA: E Gariajni	(
ID Approval: LE	and the second s

This document has been produced on behalf of Johnson Diversey by authorised personnel.

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

CERTIFICATE OF IRRADIATION Number: B

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FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd P014623 1/10/09

4/10/00



Isotron Limited

Page

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: 6/10/	/ 09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209100070	JD IPA BOTTLES 25-45kGy	179	B/No.W026853 ACTUAL38.339.3kGy
B2FLE0010999	SAMPLES	2	DOSE
B209100070		2	CUSTOMERS BATCH/CODE No.s AS ORDER
			No.P014623 DATED 30/9/2009
	Total	181	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:

For and on behalf of ISOTRON LIMITED



WICKHAIN LADOFALORIES LIMITED, Winchester Road, Wickham, Fareham, Hampshire PO17 5EU England Telephone: +44(0)1329 832511

Fax: +44(0)1329 834262

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

CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received 08-Oct-09 :

Date Tested 12-Oct-09 :

Date Completed 12-Oct-09

Purchase Order No. PO14653

Test Article

: Clearklens IPA Block 1

Sample Code

Batch Reference

: WO26853

Laboratory Reference

: LR-00895004

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	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\00141616

Certificate of Analysis - OSMM

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Flexible Medical Packaging Limited

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Date 20 Oct 2009



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire PO17 5EU England

Telephone: +44(0)1329 832511 +44(0)1329 834262

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

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CERTIFICATE OF ANALYSIS

Mr J Jackson

Date Received 08-Oct-09

Flexible Medical Packaging Limited

21-Oct-09 :

Unit 8, Hightown White Cross Industrial Estate

Date Completed

04-Nov-09

Lancaster LAI 4XS

Purchase Order No.

Date Tested

PO14653

Test Article

: Clearklens IPA Block 1

Sample Code

Batch Reference

: WO26853

Laboratory Reference

: LR-00895005

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: 649026 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

Mrs S L Wood, BSc., CBiol., MSB Laboratory Manager - Pharmaceutical Microbiology

Date 06 Nov 2009

Compliant Laboratory

GLP

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

Business Manager - Microbiology

Sample Booking Number: Flexible Medical Packaging Limited

CN\00141616

Certificate of Analysis - OSMM

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