

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01		
PRODUCT CODE	7513400		
BATCH NUMBER	W024966.		
PRODUCTION DATE	10/2008		
EXPIRY DATE	10/2010		

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

Date:	35) ii	Jo. D.	********	*******	
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Issue no. 4 Issued by W. Ashton Issue date 07,04,2006

CERTIFICATE OF IRRADIATION Number: B

0387370 00

FLEDO1

Flexible Medical Packaging Ltd

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

P013312 Cust. Ref: Date Rec'd Data:

23/10/08 31/10/08



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

Date: 31/10/	⁷ 08		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B208100659	JD IPA BOTTLES 25-45kGy	511	B/No.W024966
			ACTUAL38.0 - 40.8kGy DOSE
B2FLE0010999 B208100659	SAMPLES	10	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013312 DATED 23/10/08
	Total	521	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



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

CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received

07-Nov-08

Date Tested

11-Nov-08

Date Completed

11-Nov-08

Purchase Order No.

PO13366

Test Article

: Clearklens IPA

Sample Code

: Works Order No. 24966

Batch Reference

: 138

Laboratory Reference

: LR-00804150

Article Quantity : 2 Bottles

:

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	136% 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.

Mrs S L Wood, RSc., CBiol., MEBiol

Date 1916 2008

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

Business Manager - Microbiology

Sample Booking Number:

CN\00128455

Certificate of Analysis - OSMM

Page 1 of 1

 ${f GLP}$

Compliant

Laboratory

Flexible Medical Packaging Limited

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CERTIFICATE OF ANALYSIS

Mr J Jackson

Date Received

Date Tested

07-Nov-08

Flexible Medical Packaging Limited

13-Nov-08

Unit 8, Hightown

Date Completed

27-Nov-08

White Cross Industrial Estate Lancaster LA1 4XS

Purchase Order No.

PO13366

Test Article

: Clearklens IPA

Sample Code

: Works Order No. 24966

Batch Reference

: 138

Laboratory Reference

: LR-00804149

Article Quantity : 20 Bottles

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: 306023 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

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

Date Oa Der Lar

Business Manager - Microbiology

Sample Booking Number:

CN\00128455

Certificate of Analysis - OSMM

Page 1 of 1

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