

CERTIFICATE OF IRRADIATION

Number: **B** 0383786 00

LE001

Page 1

Flexible Medical Packaging Ltd
Unit 8
White Cross Industrial Estate
Hightown
Lancaster




Isotron Limited

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Telephone: +44 (0)1274 686011
Facsimile: +44 (0)1274 686061
Email: assistance@isotron.com
Website: www.isotron.com

LA1 4XS

st. Ref: P013162
te Rec'd 18/09/08
te: 24/09/08

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
2FLE0010081 208090548	JD IPA BOTTLES 25-45kGy	352	B/No.W024959 CUSTOMERS B/No.29732 ACTUAL: 35.8 - 39.6 kGy DOSE
2FLE0010999 208090548	SAMPLES	5	 CUSTOMERS BATCH/CODE No.5 AS ORDER No.P013162 DATED 18/9/08
Total		357	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



CERTIFICATE OF ANALYSIS

Mr J Jackson
Flexible Medical Packaging Limited
Unit 8, Hightown
White Cross Industrial Estate
Lancaster LA1 4XS

Date Received : 29-Sep-08
Date Tested : 01-Oct-08
Date Completed : 01-Oct-08
Purchase Order No. : PO13199

Test Article : Clearklens IPA
Sample Code : Works Order No. 24959
Batch Reference : 29732
Laboratory Reference : LR-00793295 **Article Quantity** : 1x 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	<0.2 EU/mL
Dilution	*	MM110/01	1/40
Spiked Recoveries	*	MM110/02	93% 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.
Product Standard Data Sheet: FM02

GLP

Compliant
Laboratory

WXB

Date 7 Oct 2008

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

Sample Booking Number: CN\00126840
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

Page 1 of 1

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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 : 29-Sep-08
Date Tested : 09-Oct-08
Date Completed : 23-Oct-08
Purchase Order No. : PO13199

Test Article : Clearklens IPA
Sample Code : Works Order No. 24959
Batch Reference : 29732
Laboratory Reference : LR-00793294 **Article Quantity** : 20x 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: 306002
Volume Tested: 20 x 50mL
Test carried out according to current Pharmacopoeias.

GLP

Compliant
Laboratory

WJL

Date 29 Oct-2008

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

Sample Booking Number: CN\00126840

Certificate of Analysis - OSMM

Page 1 of 1

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CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARLENs IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W024959
PRODUCTION DATE	09/2008
EXPIRY DATE	09/2010

TEST	METHOD	LIMITS	RESULTS
Appearance		Clear Colourless Liquid	Clear colourless liquid
Density (20°C)	GM 0110 01	0.865 – 0.885	0.879

Date: 26/09/08

QA Manager: [Signature]

QA: E. Gawn

JD Approval: [Signature]

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