

Contact address:

JohnsonDiversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 6.09.10

Product Name	CLEARKLENS IPA VH1		
Product Code	7513400		
Batch Number	WO 28342		
Production Date	2010108		
Expiry Date	2012102		

This is to certify that the above batch of product has been produced conforming to the manufacturing dossier from JohnsonDiversey in which the formula and processing instructions are defined and has been tested with the following Quality Control specification for the product.

Test	Test Method	Limits	Results
Appearance	Visual	Clear Liquid	clean Liquid
Specific Gravity (20°C)	JDM004	0.872 - 0.883	0.844

Signature / name Olgo Figiel
On behalf of Manufacturing Location







CERTIFICATE OF IRRADIATION Number: B

0458770 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

P015781 Cust. Ref: Date Rec'd 19/08/10



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

B2FLE0010081		Marie Company of the	ADDITIONAL DETAILS
B210080576	JD IPA BOTTLES 25-45kGy	432	B/No.W028372 ACTUAL DOSE37.6 - 38.8kGy CUSTOMERS BATCH/CODE No.s AS ORDER No.P015781 DATED 19/8/10
	Despatch Text:		
	8PLTS Total	432	Last Page 1 of 1

technical agreement

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

Authorising Signature: / . (If we shall be shall

For and on behalf of ISOTRON LIMITED

CERTIFICATE OF IRRADIATION Number: B

0459559 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd Date:

P015821 26/08/10 1/00/10



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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: 1/09	/10		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B210080793	JD IPA BOTTLES 25-45kGy	281	W028372
			ACTUAL DOSE37.1 - 39.1kGy
B2FLE0010999 B210080793	SAMPLES	5	CUSTOMERS BATCH/CODE NO'S AS ORDER NO P015821 DATED 25.08.10
	Despatch Text:		
	27TUBS		
	Total	286	Last Page 1 of 1
		All in acco	ordance with current

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 Fax:

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-Sep-10

Date Tested

13-Sep-10

Date Completed

13-Sep-10

Purchase Order No.

15842

Test Article

: Clearklens IPA Block 1

Sample Code

: Works Order No. 28372

Batch Reference

: 1985

Laboratory Reference

: LR-00982367

Article Quantity : 1xBottle

Test Required

: LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. 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 81%
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM02

Test carried out according to current Pharmacopoeias.

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00154143

Certificate of Analysis - OSMM

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GLP

Compliant Laboratory

Flexible Medical Packaging Limited

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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

07-Sep-10

Date Tested

09-Sep-10

Date Completed

23-Sep-10

Purchase Order No.

15842

Test Article

: Clearklens IPA Block 1

Sample Code

: Works Order No. 28372

Batch Reference

: 1985

Laboratory Reference

: LR-00982366

Article Quantity : 20xBottles

:

Test Required

: Sterility Method I: Membrane Filtration by Steritest. 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: 000011 Volume Tested: 20x50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Mr K A Barker, CBiol., MSB Business Manager

Date 22 Se, 2010

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

Sample Booking Number:

CN\00154143

Certificate of Analysis - OSMM

Page 1 of 1

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