



Contact

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

CERTIFICATE OF ANALYSIS

Date: 11/7/11

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	W03019
Production Date	06/2011
Expiry Date	06/2013

This is to certify that the above batch of product has been tested internally and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits	Results
Appearance	Visual	Clear Colourless Liquid	Clear colourless liquid
Specific Gravity (20°C)	JDM004	0.872 - 0.883	0.873

"SIGNATURE"

Name

Function Name

Please note JohnsonDiversey did change the company name to Diversey and is in the phase of implementation

CERTIFICATE OF IRRADIATIONNumber: **B**

0492897 00

FLE001

Page 1

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

**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

LA1 4XS

Cust. Ref: P017090
Date Rec'd 16/06/11
Date: 27/06/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B211060647	JD IPA BOTTLES 25-45kGy	432	B/No.W030119 ACTUAL DOSE.37.4 - 39.8...kGy CUSTOMER BATCH/CODE No.s AS ORDER No.P017090 DATED 15/6/11
Despatch Text: 8PLTS			
Total		432	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:

A handwritten signature in blue ink, consisting of a large, stylized 'Q' or 'G' shape followed by a horizontal line.

For and on behalf of ISOTRON LIMITED



Wickham Laboratories
contract analytical services

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Winchester Road, Wickham, Fareham,
Hampshire PO17 5EU England
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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: 04 Jul 11
Date Tested: 07 Jul 11
Date Completed: 07 Jul 11
Purchase Order: 17172

Test Article: ClearKlens IPA Block 1
Sample Code: Work Order No. 30119
Batch Ref: 2724
Qty Received: 1 x 900mLs
Laboratory Reference: 0001903/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	93 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	MM110/05	FM02

External Comments

Test carried out according to current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name is shown below.

Date: 08 Jul 11 13:26:59

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

Consignment: 0001903
Lancaster

Certificate of Analysis - OSMM

Print Number

P0004241

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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: 04 Jul 11
Date Tested: 16 Jul 11
Date Completed: 30 Jul 11
Purchase Order: 17172

Test Article: ClearKlens IPA Block I
Sample Code: 2724
Batch Ref: WO30119
Qty Received: 20 x 900mL
Laboratory Reference: 0001902/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Product Standard Data Sheet	MM107/03	FM03
Volume Tested	MM107/05	20 x 50 mL

External Comments

Test carried out according to current Pharmacopocias.

Approval is provided by Electronic Signature. Their name is shown below.

Date: 01 Aug 11 17:17:32

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

Consignment: 0001902
Lancaster

Certificate of Analysis - OSMM

Print Number

P0004477

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CERTIFICATE OF ANALYSIS

Date: 8/7/11

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	C2030119
Production Date	06/2011
Expiry Date	06/2013

This is to certify that the above batch of product has been tested internally and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits	Results
Appearance	Visual	Clear Colourless Liquid	Clear Colourless liquid
Specific Gravity (20°C)	JDM004	0.872 - 0.883	0.873

"SIGNATURE"

C. Pascoe

Name

Caroline Pascoe

Function Name

Pharmaroom Supervisor

Please note JohnsonDiversey did change the company name to Diversey and is in the phase of implementation

CERTIFICATE OF IRRADIATION

Number: **B**

0493842 00

FLE001

Page 1

Flexible Medical Packaging Ltd
Unit 8
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Isotron Limited

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

LA1 4XS

Cust. Ref: P017119
Date Rec'd 23/06/11
Date: 4/07/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B211070073	JD IPA BOTTLES 25-45kGy	275	B/No.W030119 ACTUAL DOSE....37.8 - 40.3....kGy
B2FLE0010999 B211070073	SAMPLES	8	 CUSTOMER BATCH/CODE No.s AS ORDER No.P017119 DATED 22/6/11
Despatch Text: 6PLTS		Total	283 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

2ND DRAFT



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CERTIFICATE OF ANALYSIS

Mr J Jackson
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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 11 Jul 11
Date Tested: 14 Jul 11
Date Completed: 20 Jul 11
Purchase Order: PO17212

Test Article: Clearklens IPA Block 1
Sample Code: -
Batch Ref: WO30119
Qty Received: 1 x 900mL
Laboratory Reference: 0001957/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	115 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	MM110/05	FM02

External Comments

Corrected Certificate of Analysis to LR-0001957/1 authorised 15 Jul 2011 11:27:36, test article name corrected and results obtained on repeat test following correct Product Standard Data Sheet. See Investigation PHM 2011 043.

External Comments

Test carried out according to current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name is shown below.

Date: 22 Jul 11 09:25:48

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

Consignment: 0001957
Lancaster

Certificate of Analysis - OSMM

Print Number

P0004370

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CERTIFICATE OF ANALYSIS

Mr J Jackson
Flexible Medical Packaging Limited
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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 11 Jul 11
Date Tested: 16 Jul 11
Date Completed: 30 Jul 11
Purchase Order: PO17212

Test Article: Clearklens IPA Block 1
Sample Code: 2724
Batch Ref: WO30119
Qty Received: 20 x 900mL
Laboratory Reference: 0001958/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Product Standard Data Sheet	MM107/03	FM03
Volume Tested	MM107/05	20 x 50 mL

External Comments

Test carried out according to current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name is shown below.

Date: 01 Aug 11 17:21:17

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

Consignment: 0001958
Lancaster

Certificate of Analysis - OSMM

Print Number

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