



#### Contact

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

### **CERTIFICATE OF ANALYSIS**

Date: 19/11/10

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	WO 28647
Production Date	11/2010
Expiry Date	11/2.012

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	Clear Colourless
		Liquid	2,201d
Specific Gravity (20°C)	JDM004	0.872 - 0.883	0.873

"SIGNATURE" C flascol

Name Caroline fascol
Function Name Pharmoon Expensor

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

CoA 7513400 v2.doc 17th August 2010 W Ashton

# CERTIFICATE OF IRRADIATION Number: B

0467349 00

FLEDD1

Flexible Medical Packaging Ltd

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P016106

Cust. Ref: Date Rec'd

3/11/10



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

Date: 12/11/	/10		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B210110203	JD IPA BOTTLES 25-45kGy	588	177 X B/No.W028644 411 X B/No <mark>.W028647</mark>
			ACTUAL DOSE36.1 - 39.5kGy
B2FLE0010999 B210110203	SAMPLES	.5	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P016106 DATED 2/11/10
÷	Despatch Text:		
	12PLTS		

Total

All in accordance with current technical agreement

593 Last Page

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

1 of

1

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

22 Nov 10

24 Nov 10

24 Nov 10

16201

+44(0)1329 834262

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

Date Received:

Date Completed:

Purchase Order:

Date Tested:

# CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8

Hightown

White Cross Industrial Estate

Lancaster

LA14XS

Test Article:

ClearKlens IPA Block 1

Sample Code:

Work Order No. 28647

Batch Ref:

2116

Qty Received:

Laboratory Reference:

1 x 900mLs 0000721/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2000 EU/mL
Spiked Recovery	MM110/01	115%
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Dilution Tested	MM110/04	1/40
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.

Sur Land.

30 Nov 10 12:05:43

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

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0000721

Certificate of Analysis - OSMM

Print Number

P0001932

Lancaster

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## **CERTIFICATE OF ANALYSIS**

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA14XS

Test Article:

ClearKlens IPA Block 1

Sample Code:

Work Order No. 28647

Batch Ref:

2116

**Qty Received:** Laboratory Reference: 20 x 900mLs 0000721/1

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
Day Book Reference	MM107/04	000058
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.

m Wood.

14 Dec 10 15:33:45 Date:

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

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0000721

Certificate of Analysis - OSMM

Print Number

P0002098

22 Nov 10

25 Nov 10

09 Dec 10

Date Received:

Date Completed:

Purchase Order:

Date Tested:

Lancaster

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