



### Contact

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

## **CERTIFICATE OF ANALYSIS**

Date: 10/12/2010

Product Name	CLEARKLENS IPA VH1		
Product Code	7513400		
Batch Number	WO 29162		
<b>Production Date</b>	11/2010		
Expiry Date	11/2012		

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" Geeniusha

Name

Function Name Pharma Supervisor

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

# CERTIFICATE OF IRRADIATION Number: B

0471013 00

FLEOO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P016237

Cust. Ref: Date Rec'd Date:

2/12/10 9/12/10



Page 1

## **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: 77 LEV 10						
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS			
B2FLE0010081 B210120190	JD IPA BOTTLES 25-45kGy	175	B/No.W029162			
			ACTUAL DOSE36.8 - 39.7kGy			
B2FLE0010999 B210120190	SAMPLES	5				
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P016237 DATED 2/12/10			
		2				
	Despatch Text:					
	4PLTS					
	Total	180	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 P017 5EU England Telephone: +44(0)1329 832511

13 Dec 10

14 Dec 10

14 Dec 10

16312

Fax: +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:

Batch Ref:

WO29162

Oty Received: Laboratory Reference:

1x900mL Bottle 0000817/4

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	107 %	
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.

Shin Lleas.

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

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0000817

Certificate of Analysis - OSMM

Print Number

P0002126

Lancaster

This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited





Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire PO17 SEU England Telephone: +44(0)1329 832511

13 Dec 10

21 Dec 10

04 Jan 11

16312

x: +44(0)1329 834262

mail@wickhamlabs.co.uk vww.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

LAI 4XS

Test Article:

ClearKlens IPA Block 1

Sample Code:

2205

Batch Ref: Qty Received: WO29162 20x900ml, Bottle

Laboratory Reference:

0000817/1

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	000071
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.

Ehm Lleas,

Date

06 Jan 11 14:33:33

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

Laboratory Manager - Pharmaceutical Microbiology

Consignment:

0000817

Certificate of Analysis - OSMM

Print Number

P0002346

Lancaster

This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited