

#### Contact address:

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

# **CERTIFICATE OF ANALYSIS**

Date: 8.10.10

Product Name	CLEARKLENS IPA VH1 7514372		
Product Code			
Batch Number	NO 28642		
Production Date	2010109		
Expiry Date	202100		

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 Liamide
Specific Gravity (20°C)	JDM004	0.872 - 0.883	9777

Signature / name Olion Tipel
On behalf of Manufacturing Location







## CERTIFICATE OF IRRADIATION Number: B

Page

0463392 00

FLE001

Cust. Ref:

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P015968

30/09/10 Date Rec'd 3.740.740



## **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: 6/10/	10		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0019081 B210100053	JD IPA BOTTLES 25-45kGy	98	B/NO: W028642 ACTUAL DOSE38.5 - 41.2kGy
B2FLE0010999 B210100053	SAMPLES  Despatch Text:	5	CUSTOMERS BATCH/CODE NO AS ORDER NO PO15968 DATED 29.09.10
	2PLTS		
	Total	103	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 PO17 5EU England Telephone: +44(0)1329 832511

11 Oct 10

13 Oct 10

27 Oct 10

PO16005

+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 2

Sample Code:

Works Order No. 28642

Batch Ref:

2110

Qty Received: Laboratory Reference:

20 Bottles 0000495/1

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	000031
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.

29 Oct 10 12:59:27

Mr K.A. Barker, CBiol, MSB Business Manager - Microbiology

Consignment: 0000495

Certificate of Analysis - OSMM

Print Number

P0001200

Lancaster

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Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire PO17 5EU England Telephone: +44(0)1329 832511

Date Received:

Date Completed:

Purchase Order:

Date Tested:

+44(0)1329 834262

11 Oct 10

13 Oct 10

13 Oct 10

PO16005

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 LA14XS

Test Article:

ClearKlens IPA Block 2

Sample Code:

Works Order No. 28642

Batch Ref: Qty Received: 2110

Laboratory Reference:

1 Bottle 0000495/2

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	75% %
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.

Shor Llaad.

21 Oct 10 17:24:12 Date:

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

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0000495

Certificate of Analysis - OSMM

Print Number

P0001032

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