



Contact

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

## CERTIFICATE OF ANALYSIS

Date: 29/11/11

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	WO 31128
Production Date	11/2011
Expiry Date	11/2013

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	0.877

"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**

0510490 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: P017741  
Date Rec'd 10/11/11  
Date: 21/11/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B211110472	JD IPA BOTTLES 25-45Kg	531	B/No.W031128  ACTUAL DOSE....36.6 - 39.2....kGy
B2FLE0010999 B211110472	SAMPLES	5	  CUSTOMER BATCH/CODE No.s AS ORDER No.P017741 DATED 9/11/11
Despatch Text:  10PLTS			
Total		536	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**  
Contract Analytical Services

Wickham Laboratories Limited  
Winchester Road, Wickham, Fareham  
Hampshire PO17 5EU England  
Telephone: +44 (0)1329 832511  
Fax: +44 (0)1329 834262  
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:** 28 Nov 11  
**Date Tested:** 30 Nov 11  
**Date Completed:** 14 Dec 11  
**Purchase Order:** 17835

**Test Article:** Clearklens IPA Block 1  
**Sample Code:**  
**Batch Ref:** WO31128  
**Qty Received:** 20 x 900mL  
**Laboratory Reference:** 0002845/1  
**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: 16 Dec 11 14:09:27

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

**Consignment:** 0002845  
Lancaster

Certificate of Analysis - OSMM

Print Number

P0000920

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**Wickham Laboratories**  
contract analytical services

Wickham Laboratories Limited,  
Winchester Road, Wickham, Fareham,  
Hampshire PO17 5EU England  
Telephone: +44(0)1329 832511  
Fax: +44(0)1329 834262

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: 28 Nov 11  
Date Tested: 30 Nov 11  
Date Completed: 30 Nov 11  
Purchase Order: 17835

Test Article: Clearklens IPA Block 1  
Sample Code:  
Batch Ref: WO31128  
Qty Received: 1 x 900mL  
Laboratory Reference: 0002845/2  
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	83 %
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: 02 Dec 11 15:00:44

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

Consignment: 0002845  
Lancaster

Certificate of Analysis - OSMM

Print Number

P0000767

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ISO  
17025

**GMP GLP FDA**  
Compliance with Good Manufacturing Practice, Good Laboratory Practice, and Food and Drug Administration regulations.

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