



Contact

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

CERTIFICATE OF ANALYSIS

Date: 27/6/11

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	W030118
Production Date	06/2011 ⁽²⁾
Expiry Date	06/2012 ³

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 *Pharmacoem Supervisor*

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

CERTIFICATE OF IRRADIATIONNumber: **B**

0492412 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

P017056

Cust. Ref: 13/06/11
Date Rec'd
Date: 21/06/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B211060511	JD IPA BOTTLES 25-45kGy	712	B/No.W030118 ACTUAL DOSE....36.3 - 40.0....kGy
B2FLE0010999 B211060511	SAMPLES	5	 CUSTOMER BATCH/CODE No.s AS ORDER No. P017056 DATED 13/6/11
Despatch Text: 14PLTS			
Total		717	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	



CERTIFICATE OF ANALYSIS

Mr J Jackson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 28 Jun 11
Date Tested: 30 Jun 11
Date Completed: 30 Jun 11
Purchase Order: P017134

Test Article: ClearKlens IPA Block 1
Sample Code: Work Order No. 30118
Batch Ref: 2700
Qty Received: 1 x 900mL Bottle
Laboratory Reference: 0001868/1
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	104 %
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: 04 Jul 11 16:09:45

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

Consignment: 0001868
Lancaster

Certificate of Analysis - OSMM

Print Number

P0004207

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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: 28 Jun 11
Date Tested: 12 Jul 11
Date Completed: 26 Jul 11
Purchase Order: PO17134

Test Article: ClearKlens IPA Block I
Sample Code: WO30118
Batch Ref: 2700
Qty Received: 20 x 900mL Bottles
Laboratory Reference: 0001867/1
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: 27 Jul 11 14:42:24

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

Consignment: 0001867
Lancaster

Certificate of Analysis - OSMM

Print Number

P0004451

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