

Contact

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

CERTIFICATE OF ANALYSIS

Date: ⁶⁷25.03.11

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	NO 29365
Production Date	03/2011
Expiry Date	03/2013

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	0.844

"SIGNATURE" *C Pascoe*

Name *Caroline Pascoe*
Function Name *Pharma room Supervisor*

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

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: P016727
 Date Rec'd 17/03/11
 Date: 24/03/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B211030626	JD IPA BOTTLES 25-45kGy	378	B/No.M029365 ACTUAL DOSE....35.6 - 36.1....kGy
B2FLE0010999 B211030626	SAMPLES	5	CUSTOMER BATCH/CODE No.s AS ORDER No.P016727 DATED 16/3/11
Despatch Text: 7PLTS			
Total		383	Last Page 1 of 1

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

Authorising Signature: *J. Goffe*

For and on behalf of ISOTRON LIMITED

FLE001

Page 1

Flexible Medical Packaging Ltd
 Unit 8
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 Roydsdale Way · Euroway Trading Estate
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LA1 4XS
 P016752
 Cust. Ref: P016752
 Date Rec'd 24/03/11
 Date: 31/03/11

Cust. Ref: P016752
 Date Rec'd 24/03/11
 Date: 31/03/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B211030883	JD IPA BOTTLES 25-45kGy	332	B/No. N029365 ACTUAL DOSE38.2 - 39.3....kGy CUSTOMER BATCH/CODE No.s AS ORDER No. P016752 DATED 23/3/11
Despatch Text: 6PLTS			
Total		332	Last Page 1 of 1

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

Authorising Signature: *J Coffey*

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 Mar 11
Date Tested: 05 Apr 11
Date Completed: 05 Apr 11
Purchase Order: -

Test Article: ClearKlens IPA Block 1
Sample Code: Work Order No. 29365
Batch Ref: 2426
Qty Received: 1 x 900mL Bottle
Laboratory Reference: 0001338/1
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	85 %
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: 05 Apr 11 16:04:05

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

Consignment: 0001338
Lancaster

Certificate of Analysis - OSMM

Print Number

P0003120

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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 Mar 11
Date Tested: 30 Mar 11
Date Completed: 13 Apr 11
Purchase Order: -

Test Article: ClearKlens IPA Block 1
Sample Code: Work Order No. 29365
Batch Ref: 2426
Qty Received: 20 x 900mL Bottles
Laboratory Reference: 0001337/1
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
Volumc Tested	MM107/05	20 x 50 mL

External Comments

Test carried out according to current Pharmacopocias.

Approval is provided by Electronic Signature. Their name is shown below.

Sarah L. Wood

Date: 14 Apr 11 17:43:09

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

Consignment: 0001337
Lancaster

Certificate of Analysis - OSMM

Print Number

P0003285

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