

Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 1/3/13

Product Name	CLEARKLENS IPA VH1	
Product Code	7514372	
Batch Number	FMP13039 33522	
Production Date	02/2013	
Expiration Date	02/2015	

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits Lower - Upper	Results
Appearance	Visual	Clear Colourless Liquid	Clar colarles
Specific Gravity (20°C)	JDM004	0.872 0.883	118cm d

On behalf of Diversey site	Name:	CHESCAR A. Mohum
Quality Manager	Position	Quality Control Inspector

This accument being issued	electronically does not bear a signature	
COA 7514372	Version: 03	Date of issuing: November 28th 2011



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 28-Feb-2013

UK32S11007294-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

ISO 11137:2006 Sterilisation of Health Care Products ISO 9001:2008 Quality Management System ISO 13485:2003 Quality System - Medical Devices

Flexible Medical Packaging Ltd Unit 8, White Cross Ind Estate Hightown Lancaster Lancashire LA1 4XS UNITED KINGDOM

All in accordance with current Technical Agreement

Customer Reference Number: P019947 **Product Description:** JD IPA BOTTLES 25-45kGv Validation Reference: 4.0621 **Quantity Received:** 712 Customer Minimum Specification kGy: 25.0 Customer Maximum Specification kGy: Customer Unit Lot/Batch Number: 707 X B/No.13039/33522 - P/REF.7514372 + 5 SAMPLES , 14 PLTS FRI 15.2.13 **Shop Order Number:** S11007294-1-1 Synergy Health Sales Part Reference: 1002734

Order Information

Irradiation Data		
Date and Time of Irradiation:	27-Feb-2013 20:53	
Reference Dose Range kGy:	36.9 - 38.3	
Calculated Minimum Dose kGy:	26.7	
Calculated Maximum Dose kGy:	40.6	

Comments: FMP 13039 -33522 000 0316 113

Irradiation Release Authorised By Synergy Health plc



Wickham Laboratories Limited, Hoeford Point, Barwell Lane, Gosport Hampshire PO13 OAU England Telephone: +44(0)1329 226600

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mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received:

04 Mar 2013

Date Tested:

06 Mar 2013

Date Test Completed:

20 Mar 2013

Purchase Order:

PO20027

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0009136/1

Test Required:

Sterility Test by Membrane Filtration (Steritest)

04/03/2013

Date Received: Test Article:

Clearklens IPA Block 2

Sample Code:

FMP13039 33522

Batch Ref: **Qty Received:**

20 x 900mL bottles

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
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM03

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

Elm Loud

Date: 21 Mar 2013 16:22:40

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

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0009136

Certificate of Analysis - OSMM

Print Number: P0009318

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Mr J Jackson

Flexible Medical Packaging Limited

Unit 8

Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received:

04 Mar 2013

Date Tested:

07 Mar 2013

Date Test Completed:

07 Mar 2013

Purchase Order:

PO20027

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0009136/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Date Received:

04/03/2013

Test Article:

Clearkiens IPA Block 2

Sample Code:

FMP13039 33522 4079

Batch Ref: Qty Received:

1 x 900mL bottle

Method Item	Result
MM110/00	<0.2 EU/mL
MM110/01	94 %
MM110/04	1/40
MM110/02	0.5 EU/mL
FG047/psd	FM02
	MM110/00 MM110/01 MM110/04 MM110/02

Comments

Test carried out according to current Pharmacopoeias.

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

Miller

Date: 11 Mar 2013 10:04:43

Mr K.A. Barker, CBiol, MSB

Business Manager - Microbiology

Consignment: 0009136

Certificate of Analysis - OSMM

Print Number: P0009037

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