



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 18/3/13

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP13045 33525
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		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear Colourless liquid
Specific Gravity (20°C)	JDM004	0.872	0.883	0.877

On behalf of Diversey site Quality Manager	Name :	<i>Abdoo O. Kichner</i>
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513400	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 08-Mar-2013

UK32S11008450-1-1

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 13485:2012 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

Order Information

Customer Reference Number:	P019967
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.0621
Quantity Received:	687
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	682 X B/No.W033525 + 5 SAMPLES , 13 PLTS LOT 3 THURS 21.2.13
Shop Order Number:	S11008450-1-1
Synergy Health Sales Part Reference:	1002734

Irradiation Data

Date and Time of Irradiation:	08-Mar-2013 20:15
Reference Dose Range kGy:	38.8 - 40.9
Calculated Minimum Dose kGy:	28.0
Calculated Maximum Dose kGy:	43.4

Comments:

Irradiation Release Authorised By Synergy Health plc

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



Wickham Laboratories
contract analytical services

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 18 Mar 2013
Date Tested: 26 Mar 2013
Date Test Completed: 09 Apr 2013
Purchase Order: 20115

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0009421/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 18/03/2013
Test Article: ClearKlens IPA Block 2
Sample Code: FMP13045 33525
Batch Ref: 4165
Qty Received: 20 x 900mL Bottles + 3 spare

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

Comments

Test carried out according to current Pharmacopoeias.

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

Suz Wood

Date: 11 Apr 2013 15:37:51

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

Consignment: 0009421

Certificate of Analysis - OSMM

Print Number: P0009798

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Wickham Laboratories

contract analytical services

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LA1 4XS

Date Received: 18 Mar 2013
Date Tested: 21 Mar 2013
Date Test Completed: 21 Mar 2013
Purchase Order: 20115

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0009421/3
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 18/03/2013
Test Article: ClearKlens IPA Block 2
Sample Code: -
Batch Ref: FMP13045 33525
Qty Received: 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	80 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM02

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 22 Mar 2013 14:22:50

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

Consignment: 0009421

Certificate of Analysis - OSMM

Print Number: P0009363

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