



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 19/12/13

Product Name	CLEARLENs IPA VH1
Product Code	7514372
Batch Number	FMP13333 35209
Production Date	11/2013
Expiration Date	11/2015

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	0.875

On behalf of Diversey site Quality Manager	Name :	C. Pascoe, O. Linckmeier
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7514372	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 13-Dec-2013

UK32S11083723-1-1

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

EN ISO 11137-1:2006 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN 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

Account Number:	100432
Synergy Health Sales Part Reference:	1002734
Customer Reference Number:	P021448
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.0621
Quantity Received:	159
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	LOT 6; 3 PLTS; THUR 05.12.13; 154 x B/NO. FMP13333 35209 + 5 SAMPLES

Irradiation Data

Date and Time of Irradiation:	12-Dec-2013 15:15
Reference Dose Range kGy:	38.9 - 40.5
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	43.0

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: 19 Dec 2013
Date Tested: 24 Dec 2013
Date Test Completed: 07 Jan 2014
Purchase Order: PO21515

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0014042/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 19/12/2013
Test Article: ClearKlens IPA BLOCK 2
Sample Code: 5049
Batch Ref: FMP13333 35209
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

Comments

See Deviation Report PHM 2013 320
Test carried out according to current Pharmacopoeias.

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

Date: 08 Jan 2014 15:24:34

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0014042

Certificate of Analysis - OSMM

Print Number: P0016658

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Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Winchester Road, Wickham, Fareham, Hampshire



Wickham Laboratories

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Date Received: 19 Dec 2013
Date Tested: 27 Dec 2013
Date Test Completed: 27 Dec 2013
Purchase Order: PO21515

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0014042/4
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 19/12/2013
Test Article: ClearKlens IPA BLOCK 2
Sample Code: 5049
Batch Ref: FMP13333 35209
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	92 %
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 and position is shown below.

Date: 30 Dec 2013 12:14:50

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0014042

Certificate of Analysis - OSMM

Print Number: P0016467 Page 2 of 2

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