



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 13/11/12

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP12292 32858
Production Date	10/2012
Expiration Date	10/2014

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		Test Colourless liquid
Specific Gravity (20°C)	JDM004	0.872	0.883	0.877

On behalf of Diversey site Quality Manager	Name :	
	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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FLE001

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Flexible Medical Packaging Ltd
Unit 8
White Cross Industrial Estate
Hightown
Lancaster

Synergy Health plc

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Bradford · West Yorkshire
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Website: www.synergyhealthplc.com



LA1 4XS

Cust. Ref: P019373
Date Rec'd 29/10/12
Date: 9/11/12

ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B212110081	JD IPA BOTTLES 25-45kGy	710	B/No.W032858 FMP12292 32858. ② 12.11.12. ROUTINE DOSE 38.7, 37.7, 36.8, 37.8kGy
B2FLE0010999 B212110081	SAMPLES	5	CUSTOMER BATCH/CODE No.s AS ORDER No.P019373 DATED 25/10/12
Despatch Text: 14PLTS			
Total		715	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 SYNERGY HEALTH PLC



Wickham Laboratories
contract analytical services

Wickham Laboratories Limited,
Hceford Point, Barwell Lane, Gosport
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Mr J Jackson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 14 Nov 2012
Date Tested: 16 Nov 2012
Date Test Completed: 30 Nov 2012
Purchase Order: PO19463

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0007648/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 14/11/2012
Test Article: Clearklens IPA Block 1
Sample Code: 3909
Batch Ref: FMP12292 32858
Qty Received: 20 x 900mL Bottles + Spares

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.

Date: 03 Dec 2012 14:29:31

Mrs P. Pham-Lengoc, BSc, MSB
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0007648

Certificate of Analysis - OSMM

Print Number: P0007260

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Wickham Laboratories

contract analytical services

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Date Received: 14 Nov 2012
Date Tested: 20 Nov 2012
Date Test Completed: 20 Nov 2012
Purchase Order: PO19463

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0007648/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 14/11/2012
Test Article: Clearklens IPA Block 1
Sample Code: 3909
Batch Ref: FMP12292 32858
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	97 %
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: 21 Nov 2012 11:55:56

Mrs P. Pham-Lengoc, BSc, MSB
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0007648

Certificate of Analysis - OSMM

Print Number: P0007031

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