



Diversey Europe BV

Maarssebroekdijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 28.06.2016

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP16130 40360
Production Date	09/05/2016
Expiration Date	EXP 09/05/2018

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	0.879

On behalf of Diversey site Quality Manager	Name :	H. H. J. P. P. P.
	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
-------------	--------------	--



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Fax: +44(0)1329 226688

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

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

Date Received: 29 Jun 2016
Date Tested: 01 Jul 2016
Date Test Completed: 15 Jul 2016
Purchase Order: 26851

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029710/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 29/06/2016
Test Article: Clearklens IPA
Sample Code: FMP16130 40360
Batch Ref: 7607
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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM03

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias

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

Date: 15 Jul 2016 16:22:18

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Fax: +44(0)1329 226688

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

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

Date Received: 29 Jun 2016
Date Tested: 30 Jun 2016
Date Test Completed: 30 Jun 2016
Purchase Order: 26851

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029710/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 29/06/2016
Test Article: Clearklens IPA
Sample Code: FMP16130 40360
Batch Ref: 7607
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	73 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 8.0 2.6.14, USP 39 <85> & JPXVI 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

Date: 30 Jun 2016 15:53:58

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 25-Jun-2016

UK33S11642644-1-1

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

EN ISO 11137-1:2015 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:	1104747
Customer Reference Number:	P026600
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	713
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV001152, FMP16130 40360, Inc 4 Samples, 13 pkts

Irradiation Data

Date and Time of Irradiation:	25-Jun-2016 16:55
Reference Dose Range kGy:	36.1 - 36.8
Calculated Minimum Dose kGy:	28.5
Calculated Maximum Dose kGy:	41.6

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 18-Jun-2016

UK33S11642641-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process
In accordance with:

EN ISO 11137-1:2015 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:	1104747
Customer Reference Number:	P026577
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	684
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV001152, , FMP16130 40360

Irradiation Data

Date and Time of Irradiation:	18-Jun-2016 10:18
Reference Dose Range kGy:	36.5 - 38.4
Calculated Minimum Dose kGy:	28.8
Calculated Maximum Dose kGy:	43.5

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 26-May-2016

UK33511626461-1-1

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

EN ISO 11137-1:2015 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:	1104747
Customer Reference Number:	P026577
Product Description:	IPA BOTTLE 25-45kGy TRIPLE VALIDATION
Quantity Received:	18
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP16130 40360, 13 plts
Other Process Details:	Actual min dose: 29.3kGy Actual max dose: 43.3kGy

Irradiation Data

Date and Time of Irradiation:	21-May-2016 17:25
-------------------------------	-------------------

26/MAY/2016

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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



Solutions in Healthcare Contract
Manufacture & Packing

VAT Registration No: GB 534 5276 43

CERTIFICATE OF CONFORMANCE

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

01524 68737
01524 67110
sales@flexible-medical.com
www.flexible-medical.com



TO:
Diversey Ltd
Amber Park Distribution Centre
Highview Road
South Normanton, Alfreton
Derbyshire
DE55 2DT

Page : 1

DATE : 01/07/16
DESPATCH NO : DN36383
FMP ORDER NUMBER : SO27932
CUSTOMER REFERENCE : 4701839302/7513400

LINE	PART NUMBER	CUSTOMER REFERENCE	QUANTITY	UNIT	LOT REF	LOT LINE
1	DEV001152	7513400	1411	EA	WO40360	
CLEARLENs IPA VH01 900ML 6 UNIT BOTTLE PK						
BATCH NO: FMP16136 40360						
Labelled with UN LQ						

CERTIFICATE OF CONFORMANCE

These goods have been manufactured in accordance with FMP Quality Systems (ISO9001:2008, ISO13485:2003, ISO14001:2004) and to the agreed specification. Responsibility for release of sterile products remains with the customer. Customers are responsible for ensuring the fitness for the purpose of the goods supplied.

FOR AND ON BEHALF OF FMP Q.A. DEPARTMENT: *C. Price*

DATE: 04/07/16



FMP® is a ClinlMed® Group Company

Registered Office: Cavell House, Knaves Beech Way, Loudwater, High Wycombe, Bucks HP10 9QY
Registered in England No. 1022136