



Diversey Europe BV

Meerpoortbroekdijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 23.05.2016

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	FHP16114 40356
Production Date	23/04/2016
Expiration Date	EXP 23/04/2018

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	0.849

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 28th 2011



Wickham Laboratories

Contract Analytical Services

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

Date Received: 23 May 2016
Date Tested: 31 May 2016
Date Test Completed: 14 Jun 2016
Purchase Order: 26607

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029087/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 23/05/2016
Test Article: ClearKlens IPA
Sample Code: FMP16114 40356
Batch Ref: 7530
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.

See Non conformance report PHM 2016 122.

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

Date: 16 Jun 2016 11:31:34

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



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Date Received: 23 May 2016
Date Tested: 24 May 2016
Date Test Completed: 24 May 2016
Purchase Order: 26607

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029087/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 23/05/2016
Test Article: Clearklens IPA
Sample Code: FMP16114 40356
Batch Ref: 7530
Qty Received: 1 x 900mL Bottles

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	87 %
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: 25 May 2016 12:53:09

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology

Certificate of Irradiation

Date Issued: 13-May-2016

UK32S11619926-1-1

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

EN ISO 11137-1:2015 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:	1002734
Customer Reference Number:	P026514
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	813
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	809 X BATCH NO: FMP16114 40356 + 4 SAMPLES MON 9TH MAY 2016 15 PLTS

Irradiation Data

Date and Time of Irradiation:	13-May-2016 17:17
Reference Dose Range kGy:	36.0 - 37.4
Calculated Minimum Dose kGy:	25.9
Calculated Maximum Dose kGy:	38.8

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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: 30-Apr-2016

UK32S11613783-1-1

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

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

Flexible Medical Packaging Ltd
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 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:	P026467
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	594
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BATCH NO: FMP16114 40356 THURS 28TH APR 2016 11 PLTS LOT 1

Irradiation Data

Date and Time of Irradiation:	29-Apr-2016 23:55
Reference Dose Range kGy:	35.6 - 36.2
Calculated Minimum Dose kGy:	25.6
Calculated Maximum Dose kGy:	37.6

Irradiation Release Authorised By Synergy Health plc

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