



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: 10 Aug 2017
Date Tested: 15 Aug 2017
Date Test Completed: 29 Aug 2017
Purchase Order: 29410

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0037276/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 10/08/2017
Test Article: Clearklens IPA
Sample Code: FMP17194 42945
Batch Ref: 8684
Qty Received: 20 x 900mL Bottles (+ 3 x 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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
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.

CBio LMSB

Date: 30 Aug 2017 12:20:47

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 17.08.17.

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	FMP 17194 62945
Production Date	13/07/2017
Expiration Date	Exp. 13/07/2019

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	0.876

On behalf of Diversey site Quality Manager	Name :	Olga Krenna, Parlyish
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513400	Version : 04	Date of issuing : April 27 th 2012
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Date Received: 10 Aug 2017
Date Tested: 11 Aug 2017
Date Test Completed: 11 Aug 2017
Purchase Order: 29410

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0037276/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 10/08/2017
Test Article: Clearklens IPA
Sample Code: FMP17194 42945
Batch Ref: 8684
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	89 %
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 9.0 2.6.14, USP 40 <85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

 BSc, CBiol, MRSB

Date: 14 Aug 2017 11:18:26

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 14-Aug-2017

UK33S11933911-1-1

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:	P029335
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	551
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17194 42945, 10 PLTS

Irradiation Data

Date and Time of Irradiation:	13-Aug-2017 20:05
Reference Dose Range kGy:	35.8 - 36.9
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	41.8

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

Certificate of Irradiation

Date Issued: 29-Jul-2017

UK33S11928152-1-1

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

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All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106573
Customer Reference Number:	29303
Product Description:	DIVER IPA B2 BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	868
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17194 42945, INCLUDING 4 SAMPLES,
<u>16PLTS</u>	

Irradiation Data

Date and Time of Irradiation:	29-Jul-2017 17:46
Reference Dose Range kGy:	34.7 - 36.6
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	41.4

Irradiation Release Authorised By Synergy Health plc

A2

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

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