



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: 18 Jan 2018
Date Tested: 26 Jan 2018
Date Test Completed: 09 Feb 2018
Purchase Order: 30310

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0040336/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 18/01/2018
Test Article: Clearklens IPA
Sample Code: FMP17348 43887
Batch Ref: 9000
Qty Received: 20 x 900mL Bottles (1 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	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.

C. Moore, MRSB

Date: 09 Feb 2018 16:32:57

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



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Date Received: 18 Jan 2018
Date Tested: 22 Jan 2018
Date Test Completed: 22 Jan 2018
Purchase Order: 30310

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0040336/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 18/01/2018
Test Article: Clearklens IPA
Sample Code: FMP17348 43887
Batch Ref: 9000
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	76 %
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 9.3 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: 22 Jan 2018 15:30:46

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 22/01/2018

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	FMP17348 43887
Production Date	14/12/2017
Expiration Date	EXP 14/12/2019

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)	DM004	0.872	0.883	0.880

On behalf of Diversey site Quality Manager	Name :	Poutyash, J. Steen
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 14-Jan-2018

UK33S12041170-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an Irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

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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:	P030240
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	560
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17348 43887, 11 PLTS

Irradiation Data

Date and Time of Irradiation:	14-Jan-2018 03:22
Reference Dose Range kGy:	33.7 - 36.6
Calculated Minimum Dose kGy:	26.6
Calculated Maximum Dose kGy:	41.4

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 06-Jan-2018

UK33S12037649-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1104747
Customer Reference Number:	P030200
Product Description:	IPA 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:	FMP17348 43887, INC 4 SAMPLES, 16 plts

Irradiation Data

Date and Time of Irradiation:	06-Jan-2018 17:39
Reference Dose Range kGy:	35.7 - 36.9
Calculated Minimum Dose kGy:	28.2
Calculated Maximum Dose kGy:	41.8

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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

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