

*Date of issuing : April 7<sup>th</sup> 2016*



# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 13 Feb 2017  
**Date Tested:** 20 Feb 2017  
**Date Test Completed:** 20 Feb 2017  
**Purchase Order:** 28377

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0033807/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 13/02/2017  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP17019 41917  
**Batch Ref:** 8203  
**Qty Received:** 1 Bottle (900mL)

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	61 %
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 39<85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

Date: 21 Feb 2017 11:42:17

Mr K.A. Barker  
Business Manager – Projects



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Ms D Henderson  
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**Date Received:** 13 Feb 2017  
**Date Tested:** 28 Feb 2017  
**Date Test Completed:** 14 Mar 2017  
**Purchase Order:** 28377

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0033807/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 13/02/2017  
**Test Article:** Clearlens IPA  
**Sample Code:** FMP17019 41917  
**Batch Ref:** 8203  
**Qty Received:** 20 Bottles (900mL) (+1 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 39 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM03

### Comments

Additional sample received 20/02/17, quantity 1 Bottle (900mL) has been allocated to lab ref 0033807/1A. 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 Mar 2017 14:34:11

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 04-Feb-2017

UK33S11804063-1-1

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:	28257
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	709
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV001928, BATCH: FMP17019 41917, 4 SAMPLE BOXES, 13PLTS

## Irradiation Data

Date and Time of Irradiation:	04-Feb-2017 09:20
Reference Dose Range kGy:	34.7 - 35.2
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	39.8

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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