



# 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:** 22 Jul 2015  
**Date Tested:** 28 Jul 2015  
**Date Test Completed:** 11 Aug 2015  
**Purchase Order:** PO24776

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0023782/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 22/07/2015  
**Test Article:** Clearklens IPA  
**Sample Code:**  
**Batch Ref:** FMP15166 38350  
**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
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: 12 Aug 2015 14:12:01

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



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**Date Received:** 22 Jul 2015  
**Date Tested:** 27 Jul 2015  
**Date Test Completed:** 27 Jul 2015  
**Purchase Order:** PO24776

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0023782/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP  
**Date Received:** 22/07/2015  
**Test Article:** Clearklens IPA  
**Sample Code:** 6689  
**Batch Ref:** FMP15166 38350  
**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	92 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM02

### Comments

Test carried out according to current Pharmacopoeias.

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



Date: 28 Jul 2015 17:10:16

Mrs S.L. Wood  
Senior Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthpic.com>

# Certificate of Irradiation

Date Issued: 20-Jul-2015

UK32S11418466-1-1

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

EN ISO 11137-1:2006 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:	P024588
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	707
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	703 X B/N FMP15166 38350 + 4 SAMPLES THUR 25 JUN 2015 13 PLTS LOT 2

## Irradiation Data

Date and Time of Irradiation:	17-Jul-2015 15:05
Reference Dose Range kGy:	37.3 - 38.3
Calculated Minimum Dose kGy:	26.9
Calculated Maximum Dose kGy:	39.8

Irradiation Release Authorised By Synergy Health plc

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



Date: 23.7.15

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

On behalf of Diversey site Quality Manager	Name :	<i>Pardysista, Amelano</i>
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA 7513400

**Version : 03**

Date of issuing : November 28<sup>th</sup> 2011