

COA 7514372	Version : 03	Date of issuing : November 28 th 2011
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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: 11 Jul 2013
Date Tested: 16 Jul 2013
Date Test Completed: 30 Jul 2013
Purchase Order: 20680

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0011252/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 11/07/2013
Test Article: Clearklens IPA Block 2
Sample Code: -
Batch Ref: FMP13176 34453
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

Test carried out according to current Pharmacopoeias.

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

Date: 01 Aug 2013 08:48:32

Mr K.A. Barker, CBiol, MSB
Business Manager - Microbiology

Consignment: 0011252

Certificate of Analysis - OSMM

Print Number: P0012404 Page 1 of 1



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 05-Jul-2013

UK32S11032613-1-1

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

ISO 11137:2006 Sterilisation of Health Care Products
 ISO 9001:2008 Quality Management System
 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

Customer Reference Number:	P020635
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.0621
Quantity Received:	298
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0 *
Customer Unit Lot/Batch Number:	293 X B/No.FMP13176/34453 + 5 SAMPLES , 6 PLTS LOT 2 MON 1.7.13
Shop Order Number:	S11032613-1-1
Synergy Health Sales Part Reference:	1002734

Irradiation Data

Date and Time of Irradiation:	05-Jul-2013 16:54
Reference Dose Range kGy:	36.8 - 37.0
Calculated Minimum Dose kGy:	26.6
Calculated Maximum Dose kGy:	39.3

*FMP13176 34453

F. Gaughan 17.07.13

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



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Date Received: 11 Jul 2013
Date Tested: 15 Jul 2013
Date Test Completed: 15 Jul 2013
Purchase Order: 20680

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0011252/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 11/07/2013
Test Article: Clearklens IPA Block 2
Sample Code: -
Batch Ref: FMP13176 34453
Qty Received: 1 x 900mL bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.20 EU/mL
Spiked Recovery	MM110/01	107 %
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 is shown below.

Susan Wood

Date: 17 Jul 2013 15:31:48

Mrs S.L. Wood, BSc (Hons), CBiol, MSB
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0011252

Certificate of Analysis - OSMM

Print Number: P0012013

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